CLINICAL PREDICTORS OF DIFFICULT LARYNGEAL EXPOSURE

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A dissertation submitted in part fulfillment of MS Branch IV, ENT examination of the Tamil Nadu Dr. MGR Medical University, to be held in March 2010

<u>Department of Otorhinolaryngology</u>
<u>Christian Medical College, Vellore</u>

<u>Certificate</u>

This is to certify that the dissertation entitled 'Clinical predictors of difficult laryngeal exposure' is the bonafide original work of Dr Roshna Rose Paul submitted in fulfillment of the rules and regulations for the MS Branch IV, ENT examination of the Tamil Nadu Dr. MGR Medical University, to be held in March 2010.

Head of Department:

Dr Mary Kurien
Professor and Head
Dept of Otorhinolarygology
Christian Medical College
Vellore, India

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Guide:

Dr John Mathew
Professor and Head
Dept of Otorhinolarygology
Christian Medical College
Vellore, India

Co-Guides:

Dr Ajoy Mathew Varghese
Assistant Professor
Dept of Otorhinolarygology
Christian Medical College
Vellore, India

Dr Mary Kurien
Professor and Head
Dept of Otorhinolarygology
Christian Medical College
Vellore, India

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And to God be the glory, great things He hath done

AIM OF THE STUDY

To identify the preoperative clinical factors those contribute to difficult laryngeal exposure in patients undergoing microlaryngoscopy.

OBJECTIVES

1.To find preoperative clinical predictors for difficult laryngeal exposure.

2. To define a simplified grading system for difficult laryngeal exposure.

PRESENT KNOWLEDGE AND REVIEW OF LITERATURE

INTRODUCTION

Microlaryngoscopy or suspension laryngoscopy has paved the pathway for endo-laryngeal surgeries be it for therapeutic or diagnostic procedures. This is done using a rigid laryngoscope. It is used to expose the larynx to access and treat vocal fold lesions that cause dysphonia / hoarseness of voice. Commonly, the rigid laryngoscope is placed through oral cavity and the larynx is exposed under general anesthesia without difficulty. Despite a significant amount of literature discussing approaches to difficult laryngeal exposure (DLE) in anaesthesia there remains a lack of consensus in describing reproducible parameters or physical findings associated with DLE.

Though many similarities can be seen between intubation and suspension laryngoscopy equating both would be overtly simplistic. For the laryngologist maximal exposure of endolarynx must be maintained for a prolonged period of time while in anaesthesia exposure is needed only during intubation. To date four articles regarding clinical predictors of difficult laryngeal exposure has been reported [1-4]

Inadequate larynx exposure can cause abandonment of the procedure, incomplete surgery, and/or unnecessary trauma to the normal vocal fold microstructure. Possible factors that lead to exposure difficulties during rigid laryngoscopy include difficulties in opening the mouth, retrognathia, a short neck, a stiff and muscular neck, obesity, macroglossia, and extension limitations of the cervical spine.

Precise physical findings associated with DLE have not yet been clearly established, and a need exists for accurate diagnostic physical findings that can serve as DLE predictors. It is logical to first identify anatomical abnormalities associated with DLE for use as presurgical predictors of the condition. The parameters found to be significant in the four reported studies are

1. Thyromandibular angle (TMA) value greater than 120 degrees in men and 130 degrees in women[1],
2. Body mass index of > 25.0 kg/m2, [2]
3. Neck circumference of > 39.5 cm [2]
4. Thyroid-mental distance of < 5.5 cm [2]
5. Neck circumference>40 cm, [3]
6. Horizontal thyromental distance<6.05cm [2, 3]
7. Sternomental distance<13.9 cm[3]
8. Modified Cormack Lehane scores (MCLS)[4]

Definition of difficult laryngeal exposure (DLE) is also not clear. It is different in different studies [1-4]. Hsiung M et al[1] defined DLE as exposure of larynx limited to posterior 1/3rd or less in spite of giving external manual pressure and using anterior commissure scope

In anaesthesia the laryngeal exposure during intubation is graded using the 5 graded modified Cormack Lehane score which is as follows [5]

Grade 1 (full view of the vocal cords),

Grade 2A (partial view of the vocal cords)

Grade 2B (only the arytenoids and epiglottis seen),

Grade 3 (only epiglottis visible)

Grade 4 (neither the epiglottis nor glottis seen).

Grade 2b and above considered difficult for DLE(2)

Roh [2] based grading of laryngeal exposure during microlaryngoscopy on the above

Grade 1: full view of vocal cords

Grade 2A: partial view of cords but anterior commissure not seen

Grade 2B: less than half of vocal cords seen

Grade3: only arytenoids visible

Grade 4: entire glottis and arytenoids hidden

Grade 3and 4 were taken as DLE

Pinar et al [3] graded glottic visualization into 2 groups after using a rigid laryngoscope of appropriate size or smaller if required and after giving external compression. Exposure of laryngeal view limited to posterior 1/3rd after the above mentioned efforts were defined as DLE group. The others were in the non DLE group Hekiert A M[4] et al used Visual analogue score (VAS) to assess degree of complexity during microlaryngeal surgery 1 being least difficult and 10 being most difficult[4]

ANATOMY OF LARYNX

The larynx is developed from the midline ventral respiratory diverticulum of the foregut known as the laryngotracheal groove. The groove appears posterior to the hypobranchial eminence. This portion of foregut posterior to diverticulum becomes oesophagus. The groove deepens and its edges fuse to form a septum. The laryngotracheal tube formed fuse caudally and extend cranially. The upper end remains separate to communicate with the pharynx. The lower portion elongates and divides dichotomously to two lobes and forms the bronchi. The portion above the division becomes trachea and uppermost portion becomes the larynx. The epiglottis develops from the posterior part of hypobranchial eminences. The thyroid cartilage develops from the 4th arch cartilage. Other cartilages and trachea are from 5th and 6th arch cartilage. The 4th arch nerve is superior laryngeal nerve and the 6th arch nerve is recurrent laryngeal nerve

Thyroid cartilage (Picture 1&2):

This consists of two pentagonal plates that meet anteriorly in the midline at an angle of 90 degree and 120 degree in female and male. It is of funnel shaped in men and cylindrical in female. Thyroid cartilage is covered by outer thick perichondrium and inner thin perichondirum. Attachment of the anterior commissure of vocal cord lacks perichondrium.

Cricoid cartilage (Picture 1&2):

This is a signet ring shaped cartilage, with a thin anterior arch and a broader posterior lamina about 20 to 30 mm high. The cricothyroid membrane connects the thyroid with the cricoid. In the anterior part this membrane is thickened and it is called the cricothyroid ligament. The inferior part is firmly attached to the trachea and superiorly, the lamina has facets for articulation with the arytenoids cartilage. This forms a crucial joint in the production of voice.

Epiglottic cartilage:

It is a leaf like hyaline cartilage whose anterior surface projects above the thyroid cartilage and faces the base of tongue and lingual tonsils. The inferior portion is narrower than the upper part. Thyroepiglottic ligament connects it to thyroid cartilage and hyoepiglotttic ligament connects it to the hyoid superiorly. Along the inferior aspect of the laryngeal surface of the petiole the epiglottic tubercle partially overhangs the anterior commissure.

Arytenoid cartilages (Picture 3):

These are paired pyramidal cartilage rests upon the cricoid lamina with two processes (vocal and muscular) an apex and a base. The concave base articulates with the cricoid cartilage in a synovial joint.

Minor cartilages (Picture 3):

The corniculate cartilage (cartilage of santorini) is located just above the apices of arytenoids. The cuneiform cartilage (cartilage of wriesberg) is found in the superior aspect of the aryepiglottic folds. These cartilages provide rigidity to the membranes, which function as ramparts that guides the food bolus away from the larynx.

Ligaments of larynx

Quadrangular membrane:

On both side of larynx, the membrane extends from the lateral edge of the epiglottis to the arytenoid cartilage posteriorly. The superior border of the membrane is a free edge corresponding to AE folds, which extends posteroinferiorly from the epiglottis to the corniculate cartilage. Each membrane's lower edge is also free and it extends from the epiglottis to the vocal process of the arytenoids corresponding to the false vocal cords which is also known as the ventricular bands. The superior and inferior edges of this membrane are thickened giving rise to the aryepiglottic ligament and the vestibular ligament.

Triangular membrane (conus elasticus):

The triangular membrane is paired and together forms the conus elasticus. Its inferior edge is firmly attached to the cricoid cartilage. Its base is located anteriorly attached to both thyroid and cricoid cartilage. Each membranes apex is attached to the vocal process of arytenoids. The free superior edge of this membrane is forming the vocal ligament. The anterior end of the vocal ligament is attached to the thyroid cartilage forming the anterior commissure tendon or called the Broyles ligament. Anteriorly the thick part of the conus elasticus forms the cricothyroid ligament.

Extrinsic muscles:

The cricothyroid muscles are located on the exterior surface of the larynx, each consist of two parts. Their anterior horizontal portion arises from the superior edge of the cricoid arch and inserts upon the posterolateral border of the thyroid cartilage. The oblique portion extends from the lateral surface of the cricoid cartilage to the inferior edge of the thyroid cartilage.

The cricothyroid muscle tilts the larynx by approximating the cricoid and thyroid anteriorly utilizing the cricothyroid joint. The cricothyroid muscle stretches the vocal fold; this muscle thins the vocal fold and sharpens its edge. These characteristic changes produced by the cricothyroid muscles in the vocal folds indicate that the cricothyroid muscles are an important determinant of the pitch of the acoustic signal of the vibrating vocal folds.

Accessory muscles:

The accessory muscles can be divided into elevator and depressor groups. The first group includes the digastric (both bellies), the stylohyoid, the geniohyoid, and the mylohyoid muscles, all of which act to pull the larynx superiorly. Additionally, contraction of the hyoglossus muscle elevates the larynx if the remainder of the tongue musculature remains fixed. The depressor muscles include the sternohyoid, sternothyroid, and omohyoid muscles, which all pull the larynx inferiorly. The thyrohyoid muscle pulls the hyoid bone and thyroid cartilage together [(6)]

ANTERIOR COMMISSURE

Embroyology

Rucci [(7)] et al studied the development of the anterior commissure region on serial sections of human larynges from embryos, fetuses, and adults. Their findings indicate that all the structures of this region derive from a single median mesenchymal band, first evident at seven to eight weeks of gestation, between the lateral laminae of the thyroid cartilage. This band of mesenchyme gives rise to all the structures along the midline of the thyroid cartilage and immediately beyond, including the intermediate lamina of the thyroid cartilage, the median process, and the connective tissue that connects the latter with the conoid ligament. This shows that Broyles' ligament (commissural tendon) derives from the dorsal part of the median process and becomes intimately connected with the surrounding structures, including the insertion fibers of the vocal muscles, from early in development. On the basis of this finding they identified an independent anterior commissure region in the adult larynx, which comprises the intermediate lamina, Broyles' ligament, the connective tissue between the Broyles' and conoid ligaments, and the insertion fibers of the vocal muscles. The interpretation of all these structures as a unified region can explain the peculiar progression pathways and evolution of commissural and cordo-commissural tumors.[7] Treatment of early glottic carcinoma (T1a, T1b, and T2a) extending into the anterior commissure is in itself controversial because of the fact that anterior commissure involvement may be associated with a higher local recurrence rate. The anatomy of the anterior commissure and its impact as a tumor barrier was the subject of several investigations and is still the subject of controversy.[8, 9] The vocal ligaments and vocalis muscles insert at the anterior commissure of the thyroid cartilage. The biomechanical function of the connective tissue of the insertion is to equalize the different elastic modules of tendons and cartilage or bone. Structures of the insertion of plica vocalis at the anterior commissure are clinically important considering the spread of carcinoma that can grow along the vocal ligament in a ventral direction. The lack of perichondrium or periosteum in the area of insertion, ossification of the thyroid cartilage and the associated vascularisation of the skeleton allow the invasion of tumours in the thyroidal skeleton.[10]

The vasculature of the anterior commissure is dependent on the medial branch of the antero-inferior laryngeal artery. Andrea et al [11] used postmortem angiography, dissection, cleared method, microangiography and histological sections, which made it possible to follow the course of the artery and determine its configuration. The results reveal separation of the supraglottis and the glottis between the thyroepiglottic ligament and the anterior commissure. The study also establishes that a separation does not exist between the glottis and the subglottis in the anterior larynx. Particular emphasis is placed on ossification of the thyroid cartilage and the relationship between the vascular network of the glottic and subglottic mucosa and the tissues immediately in front of the larynx.[11] Some authors assume the anterior commissure to represent a weak point with regard to tumor spread. This is because it is here that Broyles' ligament inserts into the thyroid cartilage and penetration might induce susceptibility to tumor invasion. The lack of perichondrium or periosteum in the area of insertion allows the invasion of tumors in the laryngeal skeleton. As only a few millimeters separate the anterior commissure mucosa from the thyroid cartilage, a small tumor on the surface actually may penetrate the cartilage[12]. Other investigators [7, 8] however, believe the anterior commissure to be a line of resistance against the cranial spread of tumors arising in the cordo-commissural region. According to Kirchner and Carter[13] and Kirchner,[14] the anterior commissure tendon may act as a tumor barrier to glottic cancer, preventing invasion of the adjacent thyroid cartilage by cancer limited to the glottic level (T1a and T1b).

DEVELOPMENT OF MICROLARYNGOSCOPY AND ENDOLARYNGEAL SURGERY

The origin and growth of laryngology is inseparably linked to the development of endoscopic surgery of the larynx. Bozzini introduced mirror laryngoscopy and Czermak, catalyzed the development of laryngology(15) Endolaryngeal surgery in the nineteenth century was therefore primarily mirror guided.

The important innovations in laryngeal exposure had been introduced by 1925. Jackson employed Kirstein's head and neck position for direct laryngoscopy in the supine position. Killian introduced the inverted-V laryngoscope blade to conform to the anterior glottal commissure and designed the laryngeal suspension that facilitated bimanual surgery. Internal distention, first described by Babington, was reintroduced in the anteroposterior dimension by Haslinger with his bivalve directoscope and in the medial-lateral dimension by Jackson with his laryngostat. Although previously used by Czermak, external counter pressure was formally described by Brunings. All laryngologists use one or more of these concepts. Zeitels and Vaughad combined them in the technique of elevated vector suspension[15]

Laryngoscope: Glottiscope

Laryngoscope is a generic term for an instrument that provides endoscopic exposure of the larynx, and it is sensible to specify laryngoscopes by the anatomic site that they are best suited to expose. A glottiscope should be appropriately shaped to the conformation of the glottal introitus, which is an isosceles triangle, not a circle or an oval. Internal distention of the supraglottal tissues facilitates maximal exposure of the superior surface of the vocal folds[16]. Ideally, a glottiscope should be intercalated between the endotracheal tube and the infrapetiole region of the supraglottis as well as between the vestibular folds to provide complete internal distention of the supraglottal structures [15]

Phonomicrosurgical Technique

Suspension microlaryngoscopy is used to resect pathologic conditions of the musculomembranous vocal folds in adults and is typically performed with general endotracheal anesthesia and paralysis. External counter pressure and internal distention are routinely used. The smallest endotracheal tube, laser-safe if necessary that adequately ventilates the patient is inserted. The endotracheal tube provides a stable point from which the laryngoscope with the largest possible lumen is intercalated between the endotracheal tube and the infrapetiole region of the supraglottis to distend the surgical field internally. Jet ventilation is not typically used, because it is not practical in many lesions and because it precludes adequate internal distention of the laryngeal introitus. The patient is placed in the classic Boyce-Jackson position with the neck flexed and the head extended at the atlanto-occipital joint.. It must be clearly understood that torsion-fulcrum laryngoscope holders use the laryngoscope tube as a lever and the maxilla as a fulcrum to expose the anterior glottis (Picture 4). It is analogous to an oar in a rowboat; the laryngoscope spatula represents the oar, and the maxilla is the oarlock [(15)]. Even if a pillow or cushion is placed under the patient's head or shoulders[(17)] to visually simulate the sniffing position, the forces are disposed incorrectly to the maxilla rather than to the mandible, tongue, and anterior pharyngeal tissues. Once the laryngoscope is suspended, external laryngeal counter pressure is first applied manually to determine its value for improving exposure. The magnitude of the pressure and vector of the force are adjusted to optimize the exposure of the lesion and the anterior glottis. It has been found that external laryngeal pressure does significantly help in visualization of vocal cords both in ENT and anaesthesia set up[(16, 18)]. If the CO, laser is to be used, both the patient and the endotracheal tube are protected in the appropriate fashion. An operating microscope fitted with a 400-mm front lens is used to examine the glottal surgical field at high magnification.

Studies have been done to assess the best possible position for suspension laryngoscopy. The sniffing position is traditionally considered optimal for direct laryngoscopic examination of the vocal folds. Hochman et al [19] examined head and neck positions associated with ideal exposure of the anterior glottal commissure with a variety of laryngoscopes. Three positions relating the atlanto-occipital and cervicothoracic vertebrae were analyzed: 1) extension-extension. 2) sniffing: extension-flexion, and 3) flexion-flexion. Regardless of the laryngoscope, the number of patients in whom complete exposure could be achieved increased gradually when the position was changed from extension-extension to extension-flexion to flexion-flexion. Complete exposure was inversely related to larger laryngoscope size. According to their data, the flexion-flexion position provides the best glottal exposure for endotracheal intubation in those patients who are anatomically predisposed to difficulty in direct examination of the glottis. Because this places the laryngoscope lumen in a vertical position, this position is inappropriate for microlaryngoscopy. The study reinforced the concept that the sniffing position is the optimal position for microlaryngoscopy because it enables the use of the largest-lumened laryngoscope. This facilitates ideal exposure of the anterior vocal folds, which is necessary for phonomicrosurgery.[19]

<u>COMPLICATIONS OF SUSPENSION LARYNGOSCOPY</u>

Although suspension laryngoscopy is routinely used in operative laryngology, no prospectively gathered data on the complications of this procedure have so far been available. Kussman et al [20]prospectively analyzed 339 consecutive procedures for intervention-related complications. The survey included preoperative dental status and assessment of postoperative dental, mucosal, and nerve injuries. Minor mucosal lesions were found in 75% of all patients. All healed spontaneously within a few days. Dental injuries occurred in 6.5% of all patients. These were more frequent in therapeutic laryngoscopy than in diagnostic procedures (6.8% versus 6.0%). Highly significant correlations were found between dental injury rate and preoperative dental disease ($p < .04$) and grade of periodontitis ($p < .001$). Temporary nerve lesions were observed in 13 patients (9 of the lingual nerve and 4 of the hypoglossal nerve). Although minor complications frequently occur during suspension laryngoscopy, it is concluded that it is a relatively safe procedure with a low risk of significant morbidity.[20]

PREDICTORS OF DIFFICULT LARYNGEAL EXPOSURE

To predict a difficult laryngeal exposure we can use anatomical or radiological criteria. The various parameters used for prediction of DLE for suspension laryngoscopy and difficult intubation are discussed below in detail.

Indirect laryngoscopy (IDL): IDL has been studied for predicting DLE and for difficult intubation. Muller et al [21]studied various screening scores for difficult laryngeal exposure and he found that the incidence of a difficult microlaryngoscopy in his study was 4.9%. All employed screening scores did not reach a satisfactory positive predictive value (PPV). The routine indirect laryngoscopy with phonation had the highest PPV (50%) of all tests and they concluded that an impossible indirect laryngoscopy can be regarded as a warning sign for a difficult microlaryngoscopic procedure[21].

Yamamoto et al [22]wanted to determine whether indirect laryngoscopy could identify patients in whom intubation was difficult. Indirect laryngoscopy was done in 2,504 patients. The Wilson risk sum score and the modified Mallampati score were also studied in a different series of 3,680 patients for comparison. These predictive methods were compared according to three parameters: positive predictive value, sensitivity, and specificity. Of 6,184 patients studied, the trachea proved difficult to intubate in 82 (1.3%). Positive predictive value (31%) and specificity (98.4%) with indirect laryngoscopy were greater than the other two predictive methods ($P < 0.01$), whereas sensitivity with indirect laryngoscopy they concluded that although in 15% of patients indirect laryngoscopy could not be performed because of excessive gag reflex, indirect laryngoscopy can serve as an effective method to predict difficult intubation.[22]

Thyromental distance (Picture 5):Thyromental distance (TMD) is measured from the thyroid notch to the mentum. A cut-off value for the TMD of 5.5 cm was the best in discriminating between patients with difficult and easy glottic visualization[2].In the study by Pinar et al the value was less than 7.15 cm[3]. In another study conducted for difficult tracheal intubation by Ayoub et al the cut off value for difficult intubation was 4 cm or less[23].

<u>Horizontal thyromental distance</u> (Picture 6):It is measured in centimeters by measuring horizontal component of thyromental distance in natural head posture. The cut off value was <4cm[2]

<u>Modified Malampatti Index (MMI)</u> (Picture 7):This test is performed with the patient in the sitting position, head in a neutral position, the mouth wide open and the tongue protruding to its maximum. Patient should not be actively encouraged to phonate as it can result in contraction and elevation of the soft palate leading to a spurious picture. Classification is assigned according to the extent the base of tongue is able to mask the visibility of pharyngeal structures

Class I: soft palate, fauces, uvula, pillars

Class II: soft palate, fauces, portion of uvula

Class III: soft palate, base of uvula

Class IV: hard palate only

The cut-off points for the airway predictors for intubation laryngoscopy were

Mallampatti III and IV [24]

But according to Roh et al[2], Pinar et al [3] and Hsiung at al [1] MMI was not found to be a good predictor for DLE while in the study by Hekiert et al [4], it was found to be a good predictor in non obese patients(BMI <30)

<u>Body Mass Index (BMI):</u> Body Mass Index (BMI) is a simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in meters (kg/m^2).The classification according to BMI is:

18.5 or less-Underweight

18.5 - 24.9 Normal

25.0 - 29.9 Overweight

30.0 - 34.9 Obese

35.0 - 39.9 Obese

40 or greater Morbid Obesity

The cutoff values according to Roh et al for predicting DLE was a body mass index of > 25.0 kg/m2[2].But Hekiert found a good correlation with a BMI of more than 30 kg/m2[4].Pinar et al [3]and Hsiung et al[1] did not find a correlation with BMI for DLE.

. A prospective, controlled study done for difficult tracheal intubation evaluated the impact of different variables on the prediction of difficult tracheal intubation in 200 morbidly obese, and 1272 non-obese patients undergoing elective surgery. High BMI did not affect the laryngoscopy difficulty and they concluded that magnitude of BMI had no influence on difficulty with laryngoscopy[25]. In another study, a cohort of 91,332 consecutive patients planned for intubation by direct laryngoscopy was retrieved from the Danish Anesthesia Database and in that they found that for difficult tracheal intubation the cut off point was 35 or more when considered alone and was found to be a weak predictor with a sensitivity of 7.5% (95% CI 7.3-7.7%) and with a predictive value of a positive test of 6.4%(95% CI 6.3-6.6%)[26]. Yet another study found a correlation between obesity and difficult tracheal intubation when used alone and in association with a MMI of grade 3 or 4[27]

<u>5-grade Modified Cormack Lehane scoring system (MCLS)</u> (Picture 8-12): The distribution of the laryngoscopy scores

The four-grade Cormack-Lehane scoring system is widely used for describing appearances at direct laryngoscopy.

Grade I: most of glottis is seen

Grade II: only posterior portion of glottis can be seen

Grade III: only epiglottis may be seen (none of glottis seen

Grade IV: neither epiglottis nor glottis can be seen

Several authors have suggested the modification of this Cormack-Lehane grading. Yentis and Lee[(5)] presented a modification that involves the subdivision of grade 2 of the original grading with no changes in the definition of the rest of the grades. This minimal adjustment creates less confusion for users of the Cormack-Lehane scores and yet better delineates increasing difficulty in laryngoscopy and intubation.

Grade 1 (full view of the vocal cord)

Grade 2A (partial view of the vocal cords)

Grade 2B (only the arytenoids and epiglottis seen),

Grade 3 (only epiglottis visible)

Grade 4 (neither the epiglottis nor glottis seen)

Grade 2b and above was considered predictor for DLE [(2, 5)]

Thyroid-mandible angle (TMA) (Picture 13): It is obtained by measuring the angle between the line of mandible angle to prominence, and the skin line from thyroid notch to mandible in the natural head posture. TMA value greater than 120 degrees in men and 130 degrees in women indicates a strong likelihood of DLE [1]

Neck circumference: This is measured at the level of thyroid notch. Value more than 39.5 cm was a predictor for DLE[2]. According to Pinar et al [3] value more than 40 cm was found to be significant.

Ratio of patient's height to TMD (RHTMD): A ratio of 23.5 for the RHTMD was found to be the optimal cut-off value to predict difficult laryngoscopy for tracheal intubation[28].It was found to be a better predictor than thyromental distance[29]

Atlanto occipital joint (AO) extension: It assesses feasibility to make sniffing or Magill position for intubation i.e. alignment of oral, pharyngeal and laryngeal axes into an arbitrary straight line. The patient is asked to hold head erect, facing directly to the front, then he is asked to extend the head maximally and the examiner estimates the angle traversed by the occlusal surface of upper teeth. Measurement can be by simple visual estimate or more accurately with a goniometer. Any reduction in extension is expressed in grades:

- Grade I : >35°
- Grade II : 22°-34°

- Grade III : 12°-21°
- Grade IV : < 12°
- Normal angle of extension is 35° or more(30)

Any A-O extension more than grade 1 will be taken as a predictor

<u>Sterno-mental distance</u> (Picture 6): Distance from the suprasternal notch to the mentum. according to Pinar et al sternum-mental distance with a value less than 13.9 cm was independently associated with difficult laryngeal exposure(3). A value of less than 12 cm is found to predict a difficult intubation(30). Another study showed that sternomental distance of 13.5 cm or less with the head fully extended on the neck and the mouth closed provided, using discriminant analysis, the best cut-off point for predicting subsequent difficult laryngoscopy. A sternomental distance of 13.5 cm or less had a sensitivity, specificity, positive and negative predictive values of 66.7%, 71.1%, 7.6% and 98.4%, respectively(31)

MATERIALS AND METHODS

a**) Study Design**:

This was a prospective, non randomized, non controlled, descriptive study.

b) Operational Definitions:

Grade 1: Full view of vocal cords

Grade 2: Partial view of vocal cords - Anterior commissure not seen but seen on external compression

Grade 3: Anterior commissure not seen even with external compression

Grade 4: Less than half of vocal cords seen even with external compression

Grade 3 and 4 are being taken up as DLE (Difficult laryngeal exposure).

c) **Inclusion criteria:**

All patients above the age of 18 years undergoing microlaryngoscopy in Christian Medical College, Vellore.

d) **Exclusion criteria:**

1. History of surgeries in the neck including tracheostomies
2. Previous radiation to head and neck region
3. Lesions obscuring vision of anterior commissure

.

e) **Informed Consent:**

Informed consent was taken in patient’s language from all being enrolled in the study.

The consent forms are attached as Appendix A.

f) **Methods:**

Patient was subjected to a detailed presurgical evaluation which include age , sex, weight, height, thyromental distance, horizontal thyromental distance, sternomental distance, mallampatti score, neck circumference, thyromandibular angle and atlanto-occipital extension. , MCLS grading (by anaesthetist) the grade of scopy, complications and who did the surgery (registrar/consultant) will be assessed intraop. All data collected was entered in a performa.

All parameters except MCLS were measured for each patient prior to surgery. The parameters were assessed with the patient sitting upright with head in natural position without swallowing at the end of expiration. Natural head posture is defined as patient looking into his or her eyes reflected in a mirror located at eye level. All parameters except MCLS were assessed by the principle investigator.

The MCLS scoring was assessed by the anaesthetist during intubation.

The grade of scopy was assessed during surgery by the respective surgeons who were unaware of the pre operative parameters.

Complications during procedure were also noted. All data were recorded and the results were analyzed to note the predictive value of the various preoperative parameters.

g) **Instruments:**

The TMD, HMD, SMD was measured using a standard 15 cm and 30 cm measuring scales. A-O extension and TMA were measured using a goniometer. Neck circumference was measured using a standard measuring tape. MCLS was assessed after visualization using a Macintosh curved blade laryngoscope. Microlaryngoscopy was done by Storz laryngoscope. Cases in which the scopies were difficult we used an anterior commissure scope.

h) **Microlaryngscopy:**

The patient was intubated and positioned under general anaesthesia in the classic Boyce Jackson sniffing position. Storz microlaryngoscope was inserted and suspended with the rod and ring chest support (Picture 14, 15). Under operating microscopic vision larynx examined and appropriate procedures were done.

i) **Calculation of Sample Size**

Sample size for this descriptive study was calculated as 10 per parameter being assessed. 10x11=110

j) **Statistical Analysis:**

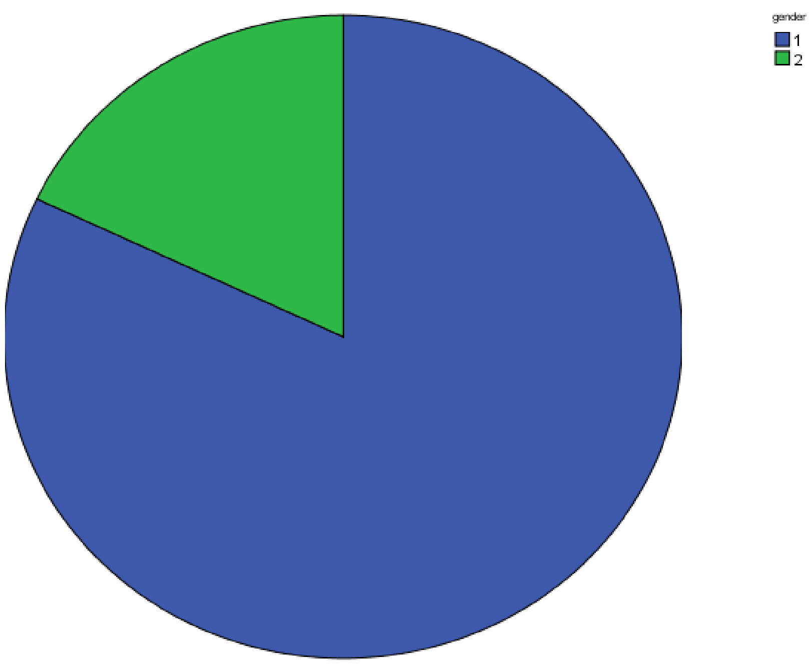
All statistical analyses were performed using Statistical Package for Social Sciences 16.0 for windows (SPSS Inc, Chicago, IL). Descriptive statistics such as mean ± standard deviation and frequency with percentage were used to present continuous and categorical variables respectively. Independent samples‘t’ test was used to compare continuous variables and chi-square test was used to assess the association between categorical variables. Predictors that were significantly associated with the outcome at 10% significance level were taken into a multivariable logistic regression model to compute adjusted odds ratios. Continuous predictors were dichotomized based on diagnostic test criteria (sensitivity, specificity and ROC curve).

RESULTS AND ANALYSIS

1. Patient profile:

Gender distribution: 117 patients were enrolled in this study. Out of these 117 patients admitted to undergo microlaryngoscopy 96 (82.05 %) were men and 21 (17.95 %) were women.

Figure 1

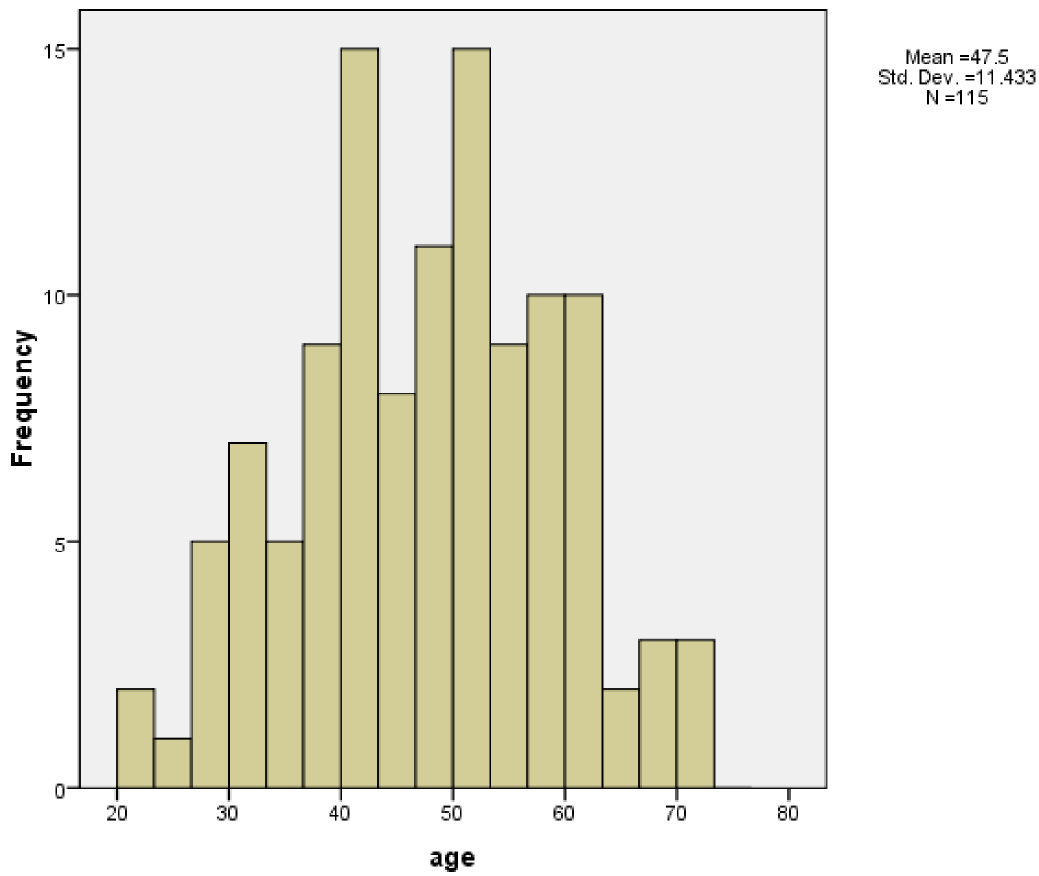


1: Men   2: Women

2. Age distribution:

The age distribution of the patients included in the study varied from 20 years to 71 years. The mean age was 47.5. Our study did not include patients below 18 years of age.

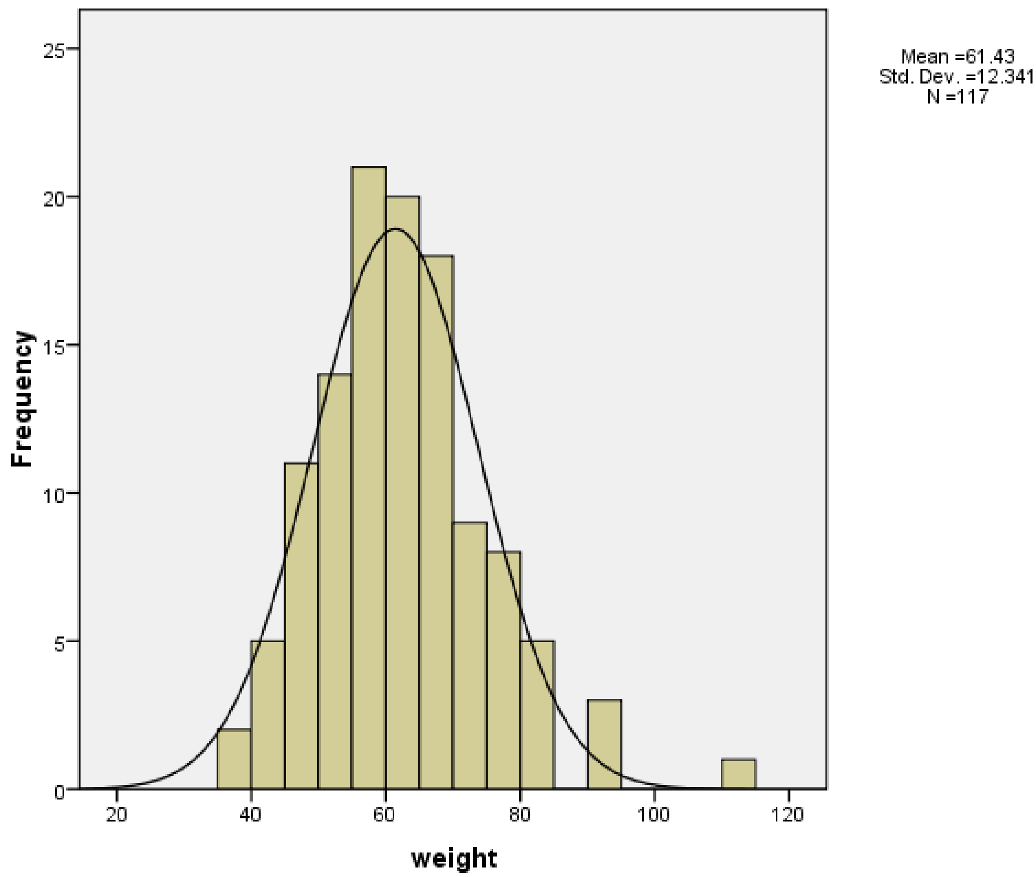
Figure 2



3. Weight:

The weight of the patients ranged from 37.5 kg to 110 kg. The mean weight was 61.43 kg.

Figure 3



4. <u>Height</u>:

The height of the patients included in the study ranged from 143 cm to 186 cm. The mean height was 163.8 cm.

Figure 4

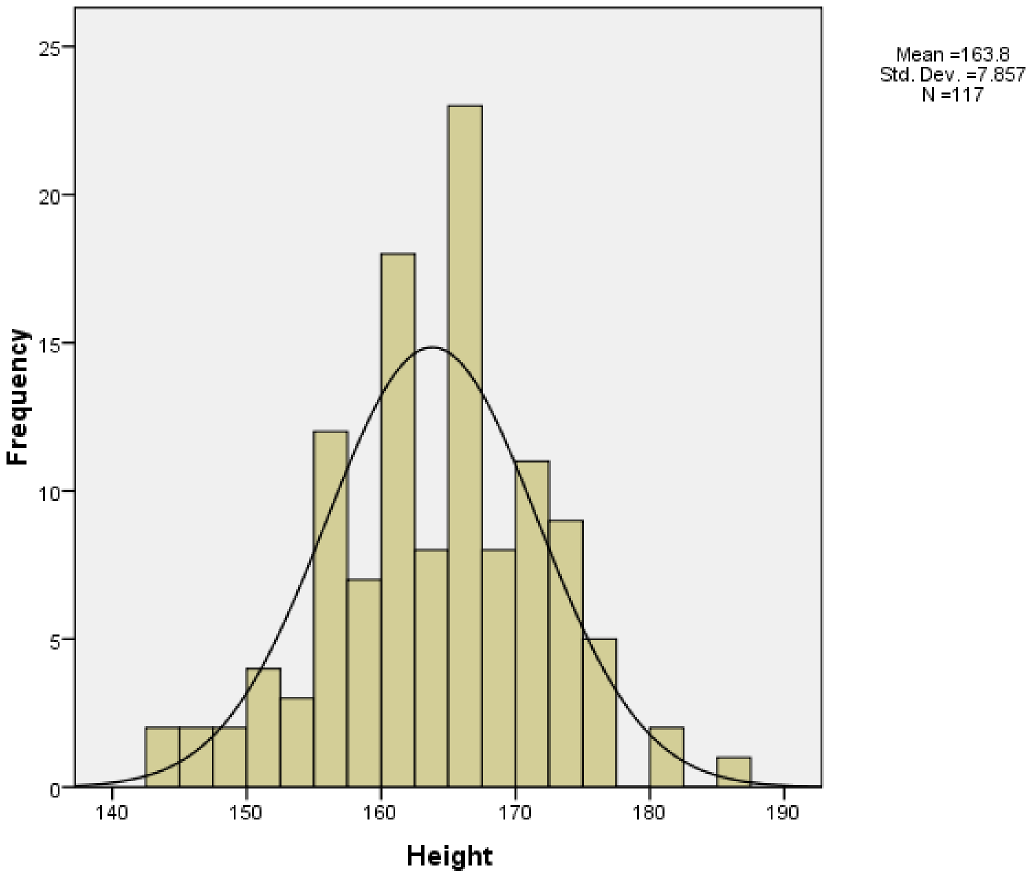


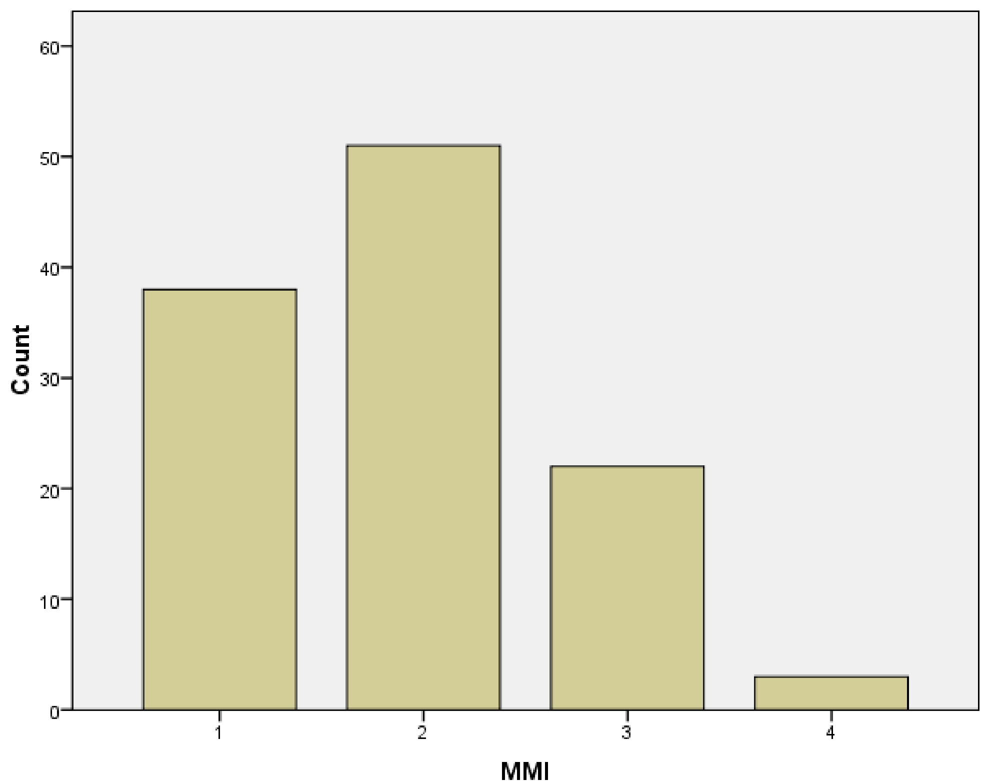
Fig 4

5<u>. Modified Mallampatti Index (MMI)</u>: There are 4 grades in MMI. Out of the 117 patients seen MMI was measured for 114 of the patients. 3 values were missing.

Table1.

Grade	**Number**	**Percentage**
Grade 1	38	32.5
Grade 2	51	43.6
Grade 3	22	18.8
Grade 4	3	2.6

Figure 5



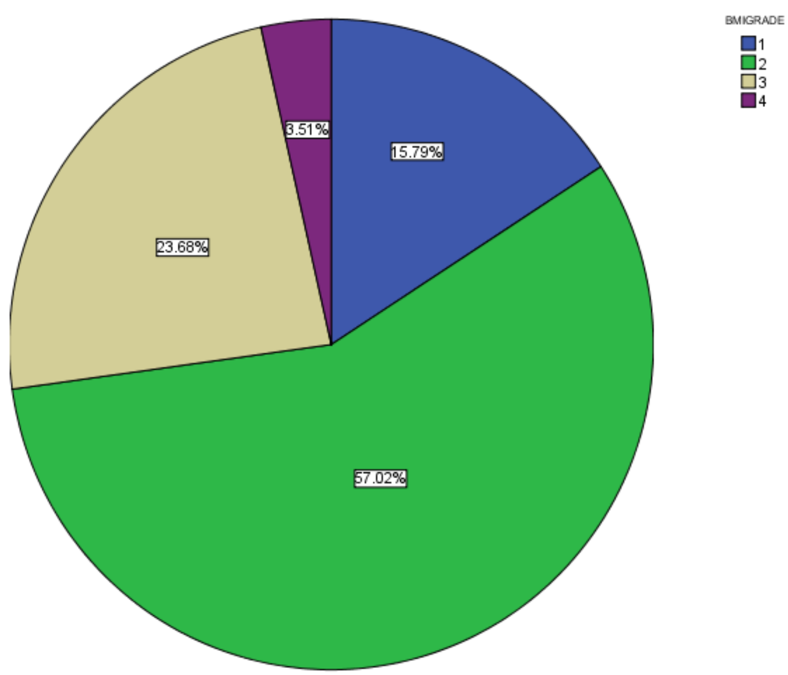
6. Body mass index (BMI):

BMI was calculated for 114 of the 117 patients enrolled in the study.3 values were missing 3.6 %). 18 (15.79 %) patients had a BMI of grade 1, 65 (57.02 %) had a normal BMI between 18.5 to 24.9, while 4 (3.51 %) people fell in the obese category

Table 2

Body mass index	Numbers	Percentage
18.5 or less-Underweight-1	18	15.79
18.5 - 24.9 Normal-2	65	57.02
25.0 - 29.9 Overweight-3	27	23.68
30.0 - 34.9 Obese-4	4	3.51

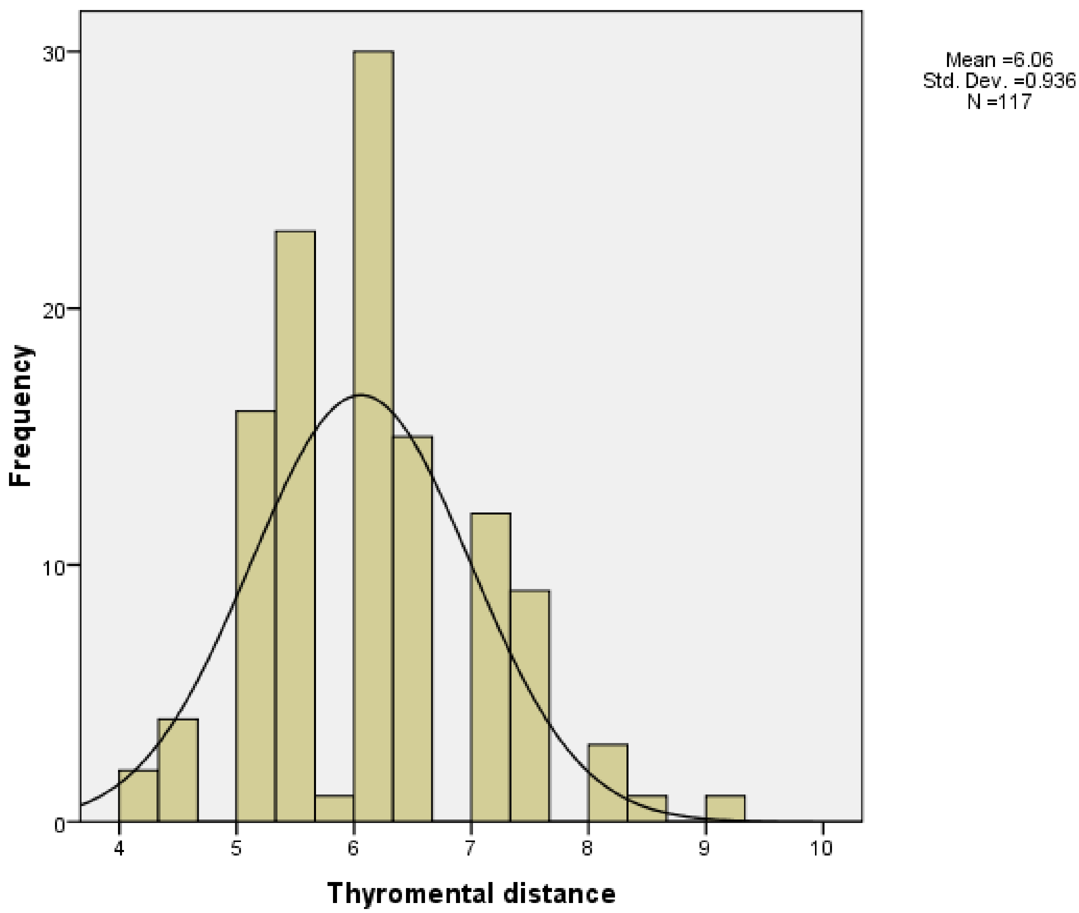
Figure 6



7. <u>Thyro mental distance (TMD):</u>

The thyromental distance measured in the 117 patients ranged from 4 cm to 9 cm with mean of 6.06 cm.

Figure 7



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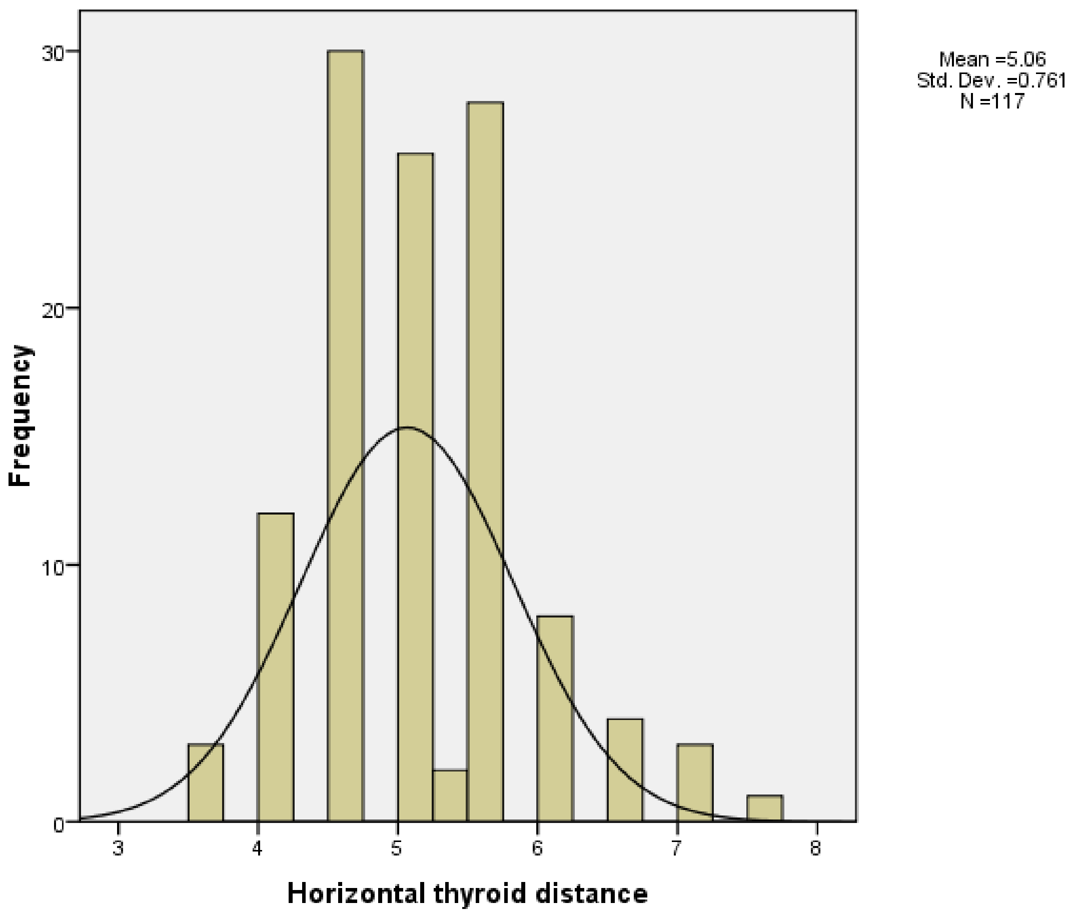
8. <u>Horizontal thyroid distance (HTD):</u>

The horizontal thyroid distance in the 117 patients ranged from 3.5 cm to 7.5 cm with a mean of 5.06 cm

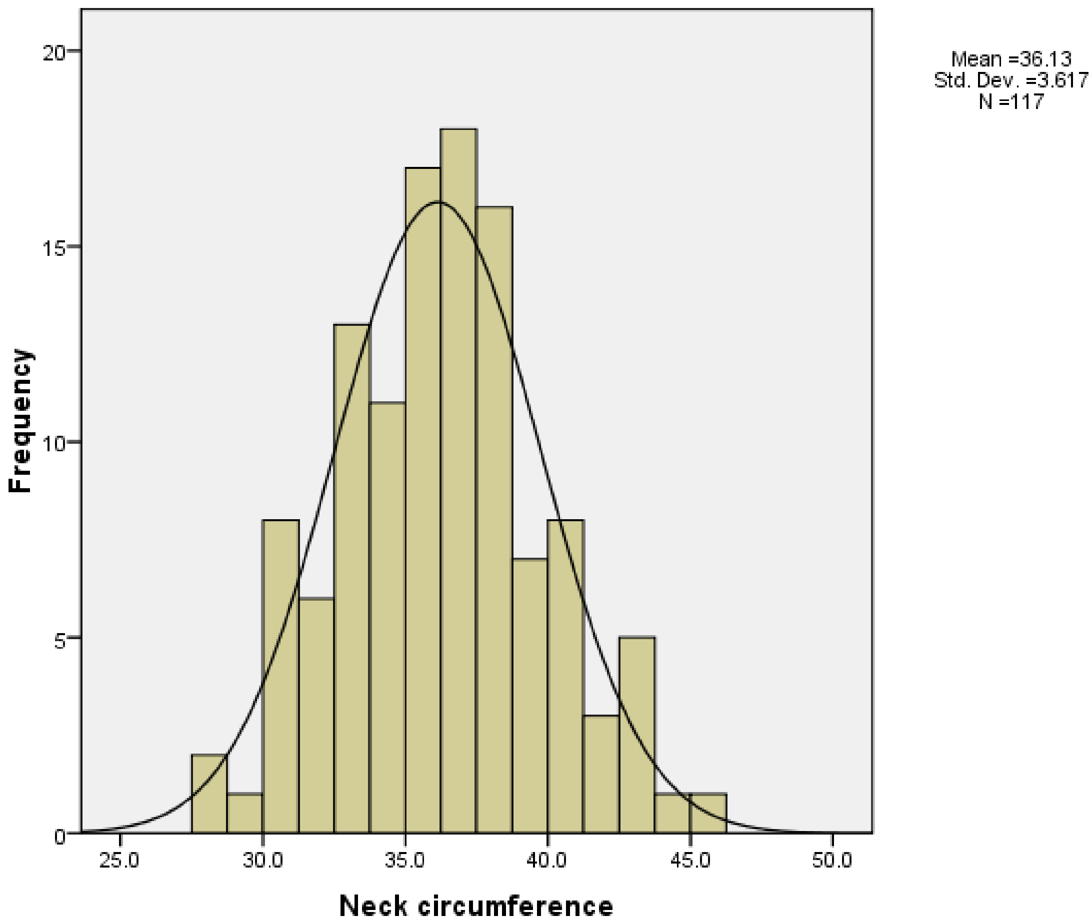
Figure 8



9. Neck circumference:

Neck circumference for the patients ranged from 28.5 cm to 46 cm with a mean of 36.13 cm

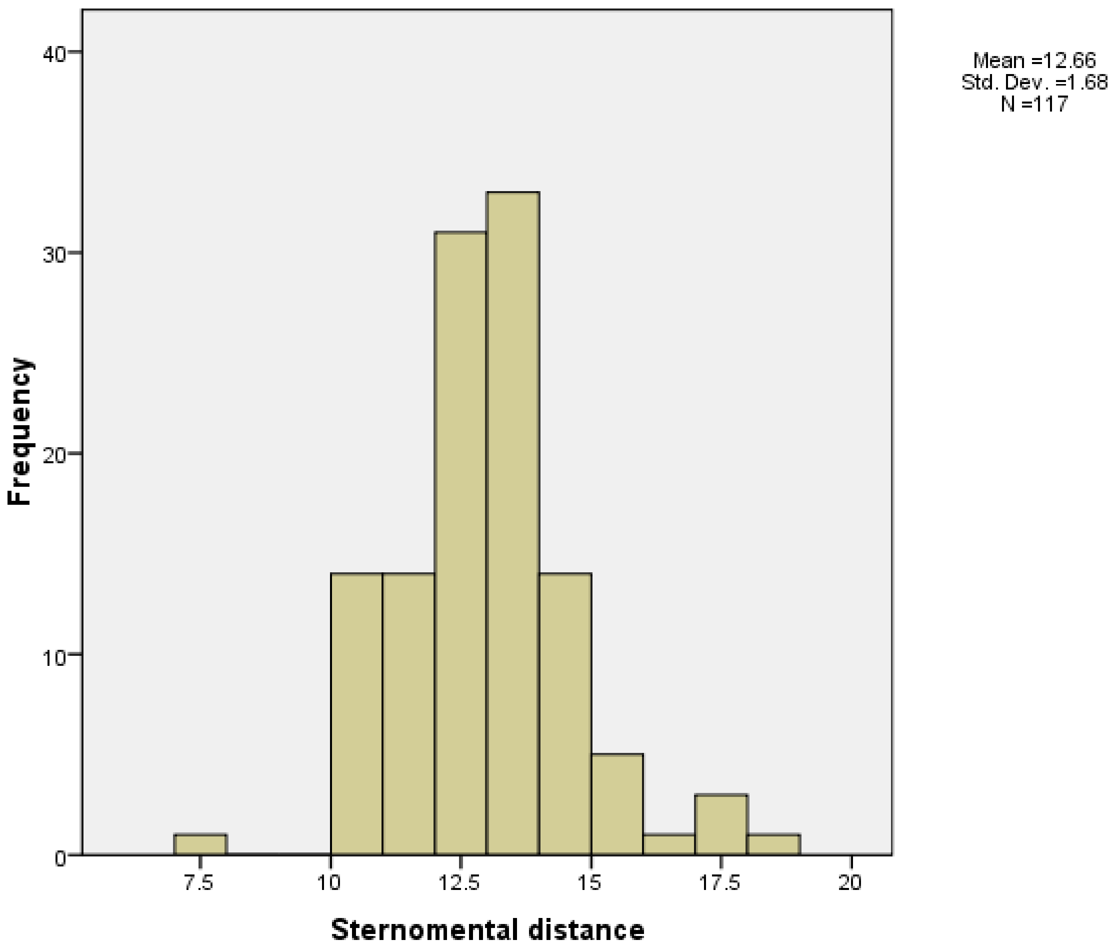
Figure 9



10. Sternomental distance (SMD):

The values of TMD ranged from 7 to 18 cm with a mean of 12.66 cm. The standard deviation was 1.68.

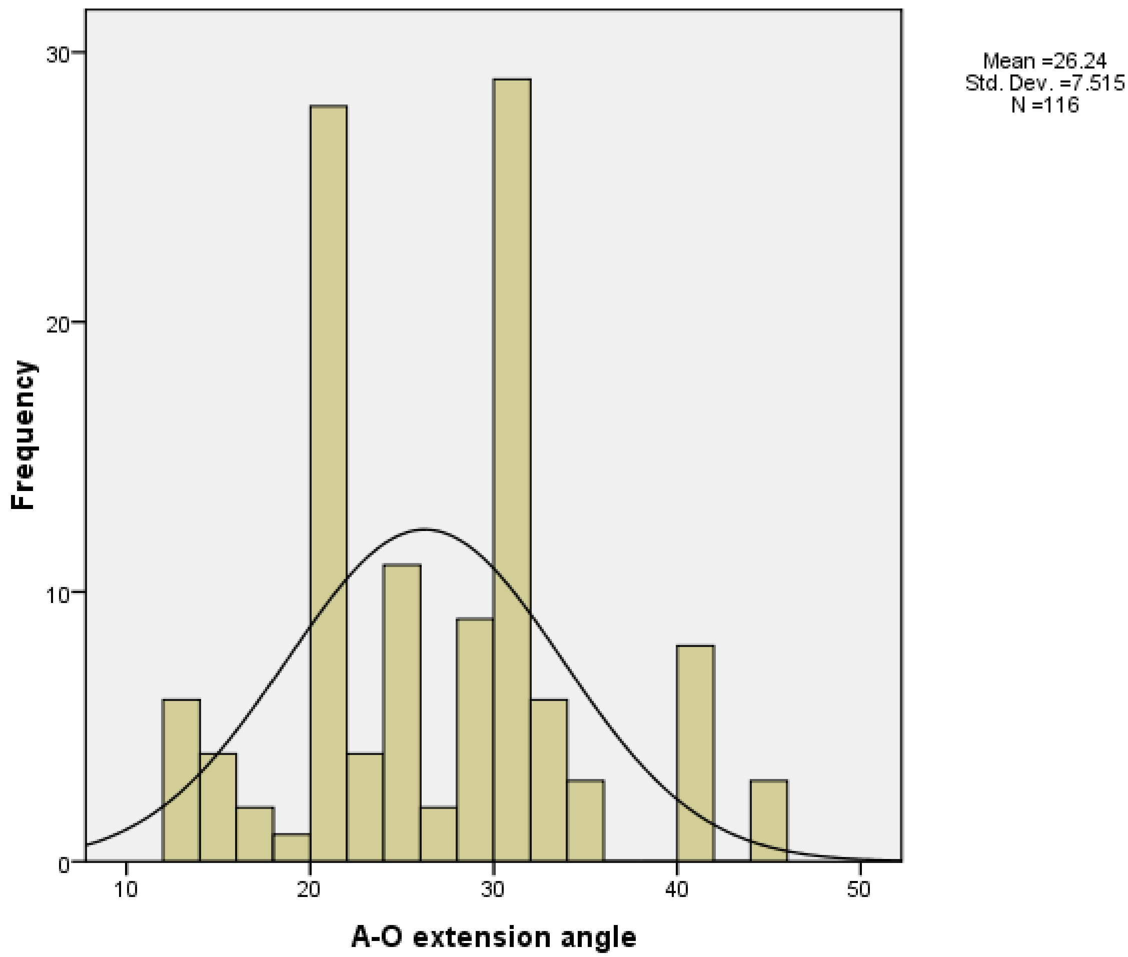
Figure 10



11. Atlanto-occipital extension (A-O extension):

The A-O extension was measured in degrees and the values ranged from 12 to 45 degrees with a mean of $26.24^{0.}$ The standard deviation was 7.515.

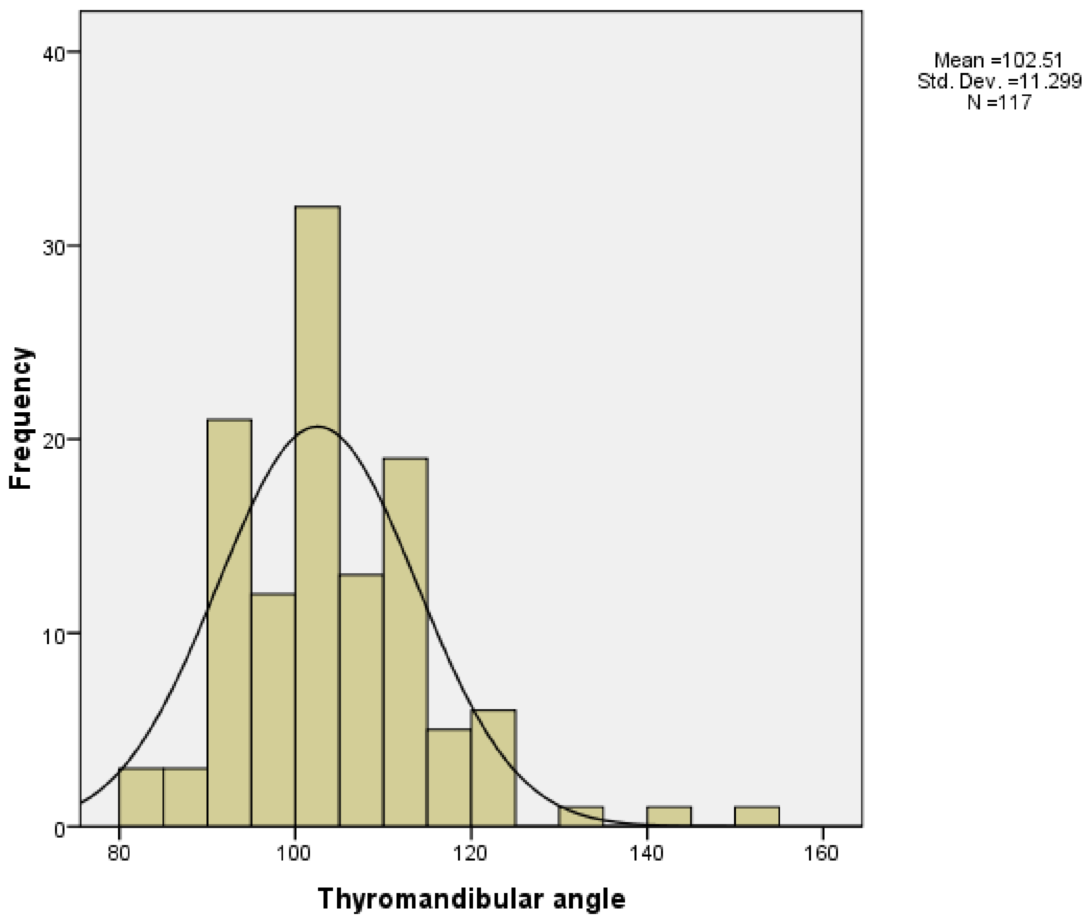
Figure 11



12. <u>Thyromadibular angle (TMA):</u>

The thyromandibular angle ranged from 80 to 150 degrees with a mean of 102.51 degrees. The standard deviation was 11.29.

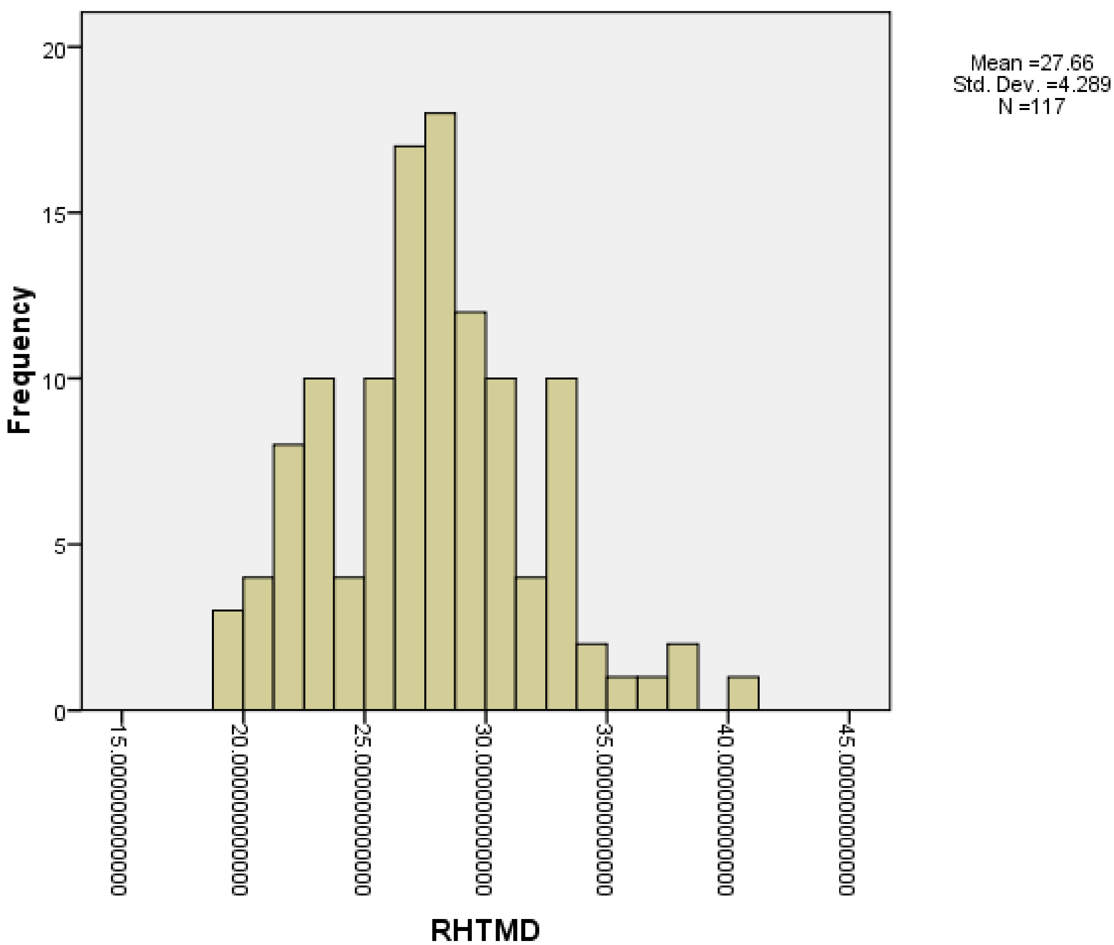
Figure 12



13. Ratio of height to thyromental distance (RHTMD):

The ratio of height and thyromental distance in centimeters ranged in the study from 19 to 40.5 cm with a mean of 27.66 cm. The standard deviation is 4.289.

Figure 13



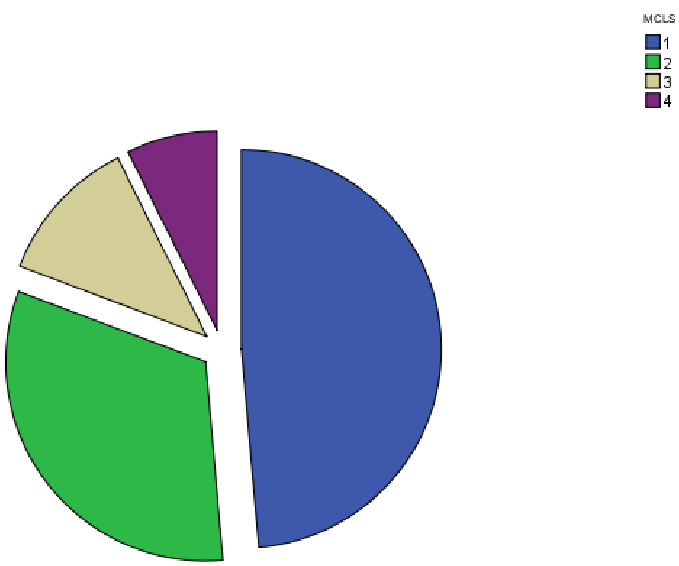
14. Modified Cormack Lehane scoring system (MCLS):

The MCLS scoring has 5 grades. In our study 8 values were missing and we had come across only the 1st 4 grading.

Table 3:

MCLS	Numbers	Percentages
Grade1	53	45.3
Grade 2a	35	29.9
Grade 2b	13	11.1
Grade 3	8	6.8

Figure 14

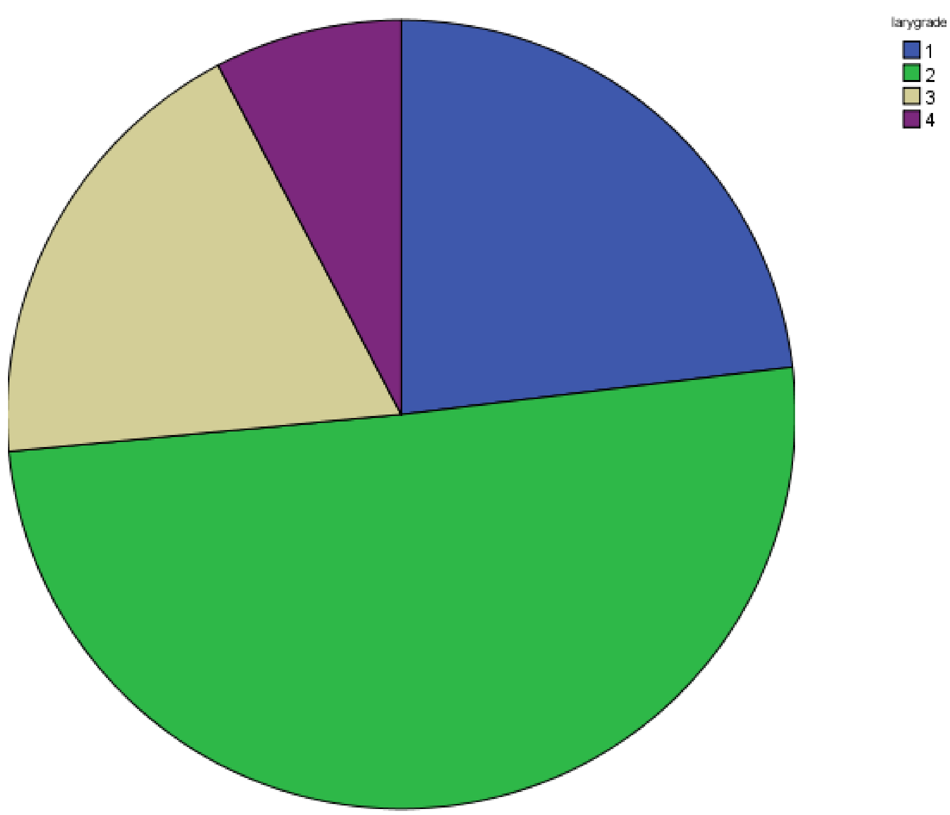


<u>Laryngoscopy grade</u>: Out of the 117 cases analyzed the distribution of laryngeal exposure grades were as follows.

Table 4:

Laryngeal exposure	Numbers	Percentage
Grade 1	27	23.1
Grade 2	59	50.4
Grade 3	22	18.8
Grade 4	9	7.7

Figure 15

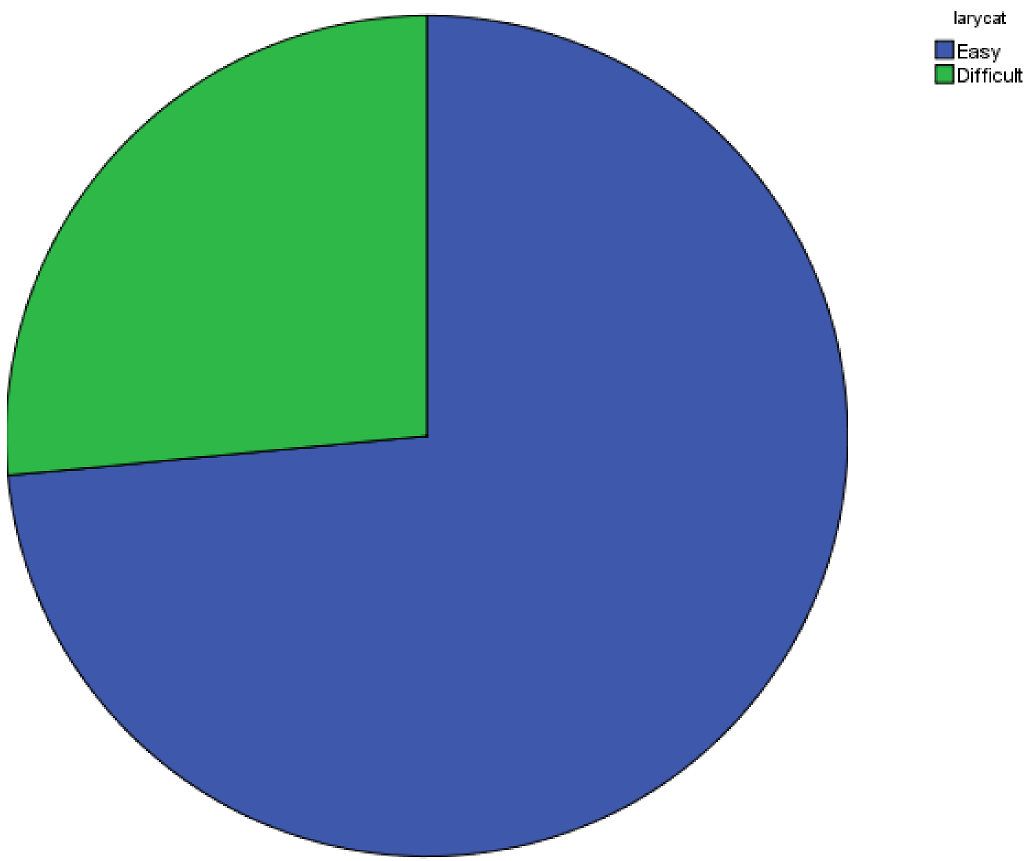


Grade 3 and 4 were considered as difficult laryngeal exposure (DLE)

Table 5:

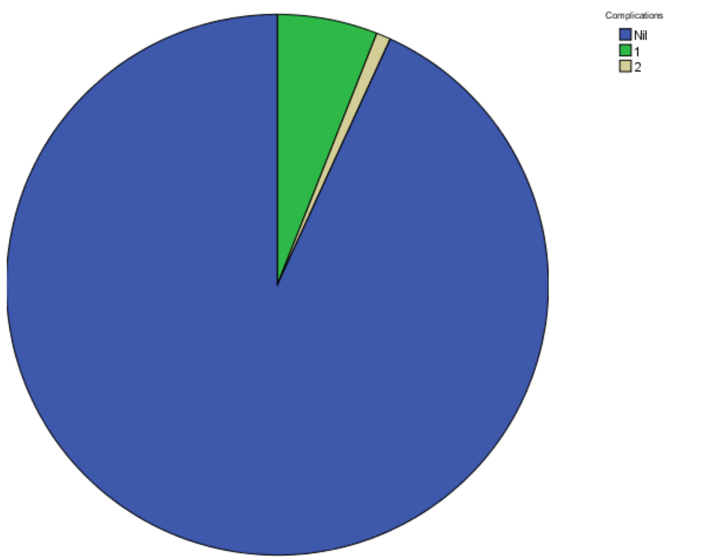
Laryngeal exposure	Numbers	Percentage
Easy (1&2)	86	73.5
Difficult (3&4)	31	26.5

Figure 16



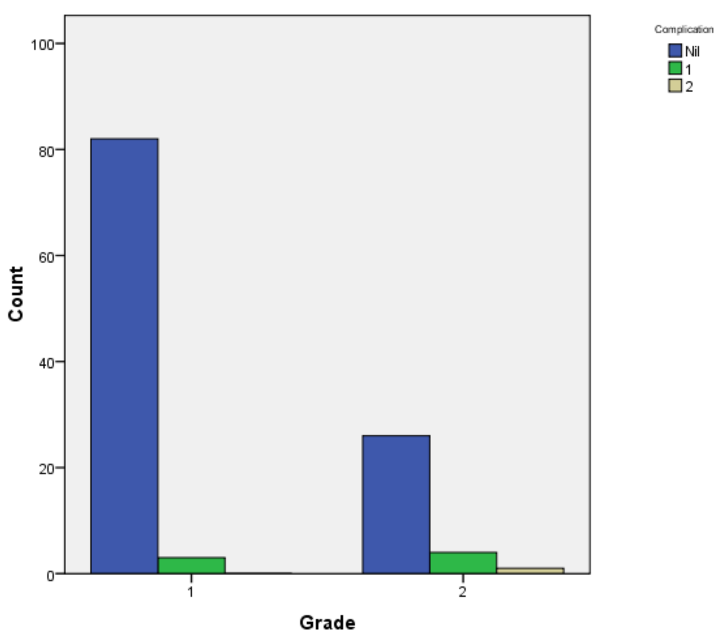
<u>Complications:</u> Of the 117 cases only 7 patients had complications associated with the procedure. 6 had a tonsillolingual sulcus tear and 1 had a tooth injury. Of these 7 cases 6 had a difficult laryngeal exposure while 1 had a normal scopy but still had a tonsillolingual sulcus tear.

Figure 17



Green: Tear, Brown: Tooth injury

Figure 18



Univariate analysis:

Table 6:

Variable	Outcome		P-value
	Easy	Difficult	
Neck circumference †	35.51 ± 3.58	37.86 ± 3.26	0.002
A-O extension	27.64 ± 7.27	22.65±7.078	0.001
BMI	22.36 ± 3.80	23.91 ± 4.34	0.068
Thyromental distance	6.11 ± 1.01	5.87 ± 0.68	0.217
Horizontal thyroid distance	5.11 ± 0.78	4.93 ± 0.72	0.250
Sternomental distance	12.65 ± 1.60	12.62 ± 1.93	0.925
Thyromandibular angle	101.87 ± 10.48	104.19 ± 13.47	0.331
Ratio of height to TMD	27.35 ± 4.59	28.55 ± 3.30	0.185
Gender ‡	68 (79.06%)	28 (90.3%)	0.16
MMI‡	70 (84.3%)	19 (61.3%)	0.008
MCLS‡	75 (91.5%)	13 (48.1%)	0.000

† Continuous variables as mean ± standard deviation

‡ Categorical variables as frequency (percentage)

Of the eleven parameters, eight were continuous variables and three were categorical variables. Using Independent sample t test for continuous and chi square ratio for categorical 4 of the 12 were found to have a p value of less than 0.05. Along with these four, BMI was also taken up for analysis though p value was 0.068 as it was presumed to be a good predictor.

Table 7:

Variable	Outcome		P-value
	Easy	Difficult	
MMI‡	70 (84.3%)	19 (61.3%)	0.008
MCLS‡	75 (91.5%)	13 (48.1%)	0.000
Neck circumference	35.51 ± 3.58	37.86 ± 3.26	0.002
A-O extension	27.64 ± 7.27	22.65±7.078	0.001
BMI	22.36 ± 3.80	23.91 ± 4.34	0.068

Categorized bivariate analysis:

Using ROC curve, the cut off values of the significant parameters in the continuous variables were identified. For BMI we took the definition of obesity (25) as a cut off. For MCLS grade 2b and above were taken as a predictor and for MMI, grade 3 and 4 were taken as a predictor.

Table 9:

Variable	Cut off value	Sensitivity	Specificity
A-O extension	19.5 degrees	80 %	8.3 %
Neck circumference	34.25 cm	90 %	38%
BMI	25		
MCLS	2b and above		
MMI	Grade 3 and 4		

1. Atlanto-occipital extension vs laryngoscopy grade:

Figure 19

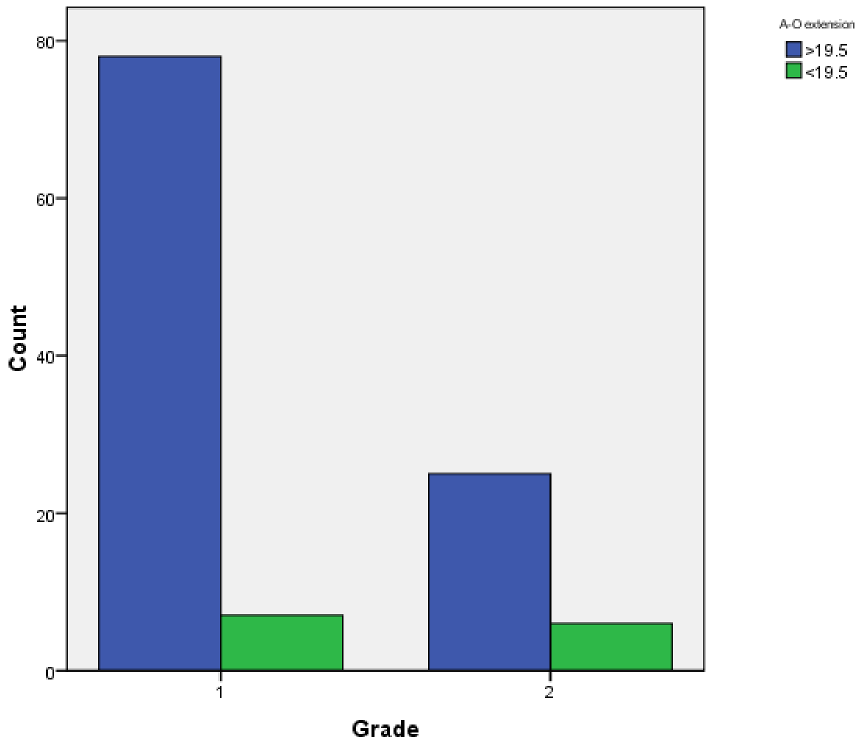


Table 10

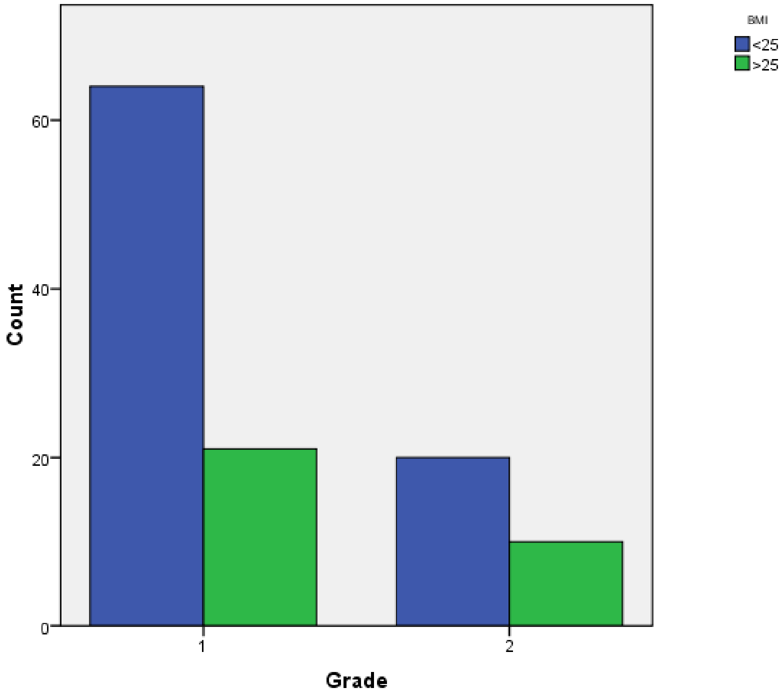
A-O extension vs laryngoscopy grade

		A-O extension		Total
		>19.5	<19.5	
Grade	Easy	79(91.9%)	7(8.1%)	86
	Difficult	25(80.6%)	6(19.4%)	31
Total		104	13	117

Out of the the 117 cases 86 had an easy scopy while 31 had difficult scopy. Of the 86 easy scopies, 7 had an A-O extension of less than 19.5 ^{0} while in the 31 difficult scopies, 6 had A-O extension less than 19.5 ^{0}

2. **Body mass index**

Figure 20



		BMI		Total
		<25	>25	
Grade	Easy	64(74.4%)	21(24.4%)	85
	Difficult	20(64.5%)	10(32.3%)	30
Total		84	31	115

Out of the 117 cases, BMI was calculated for 115 of patients. In the 85 easy scopies, 64 patients had a BMI of less than 25 while 21 had a BMI of more than 25. In the DLE group, 20 had a BMI of less than 25 and 10 had a BMI more than 2.

3. Modified Cormack Lehane scoring system (MCLS):

Figure 21

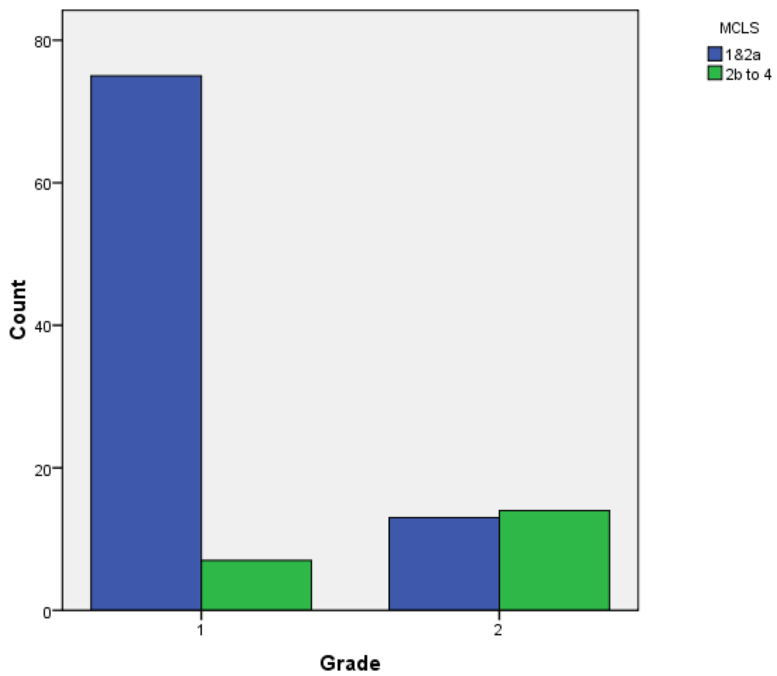


Table 11:
MCLS vs laryngoscopy grade

		MCLS		
		1&2a	2b&above	Total
Grade	Easy	75(87.2%)	7(8.1%)	82
	Difficult	13(41.9%)	14(45.2%)	27
Total		88	21	109

Out of the 117 cases, MCLS was calculated for 109 of patients. In the 82 easy scopies, 75 patients had a MCLS of 1 and 2a while 7 had a grade of more than 2b. In the DLE group, 13 had a MCLS of less than 2b and 14 had a MCLS grade 2b and above.

4. **Neck circumference:**

Figure 22

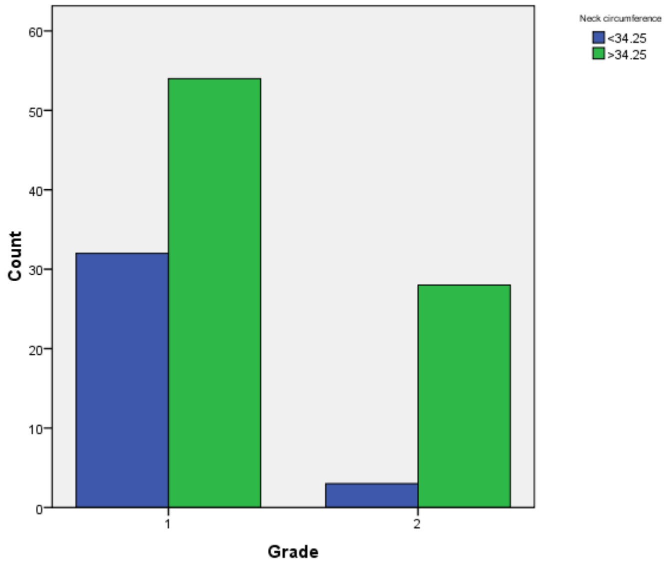


Table 12

Neck circumference vs laryngoscopy grade

		Neck circumference		
		<34.25	>34.25	Total
Grade	Easy	32(37.2%)	54(62.8%)	86
	Difficult	3(9.7%)	28(90.3%)	31
Total		35	82	115

Out of the 117 cases, neck circumference was calculated for 115 of patients. In the 86 easy scopies, 32 patients had a neck circumference of less than 34.25 while 54 had a value of more than 34.25. In the DLE group, 3 had a value of less than 34.25 and 28 had a value of more than 34.25.

5. **Modified Mallampatti index (MMI):**

Figure 23

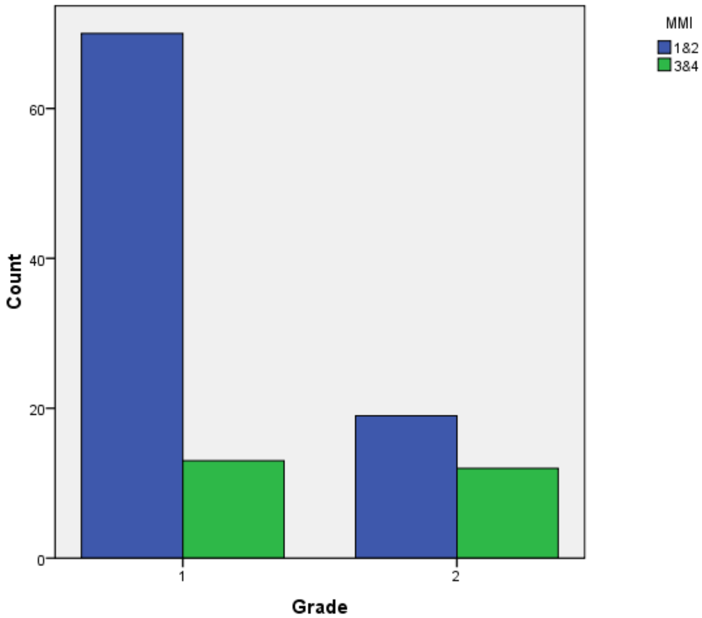


Table 13

MMI vs laryngoscopy grade

		MMI		Total
		1&2	3&4	
Grade	Easy	70(81.4%)	13(15.1%)	83
	Difficult	19(61.3%)	12(38.7%)	31
Total		89	15	114

Out of the 117 cases, MMI was calculated for 114 patients. In the 83 easy scopies, 70 patients had a MMI of 1 and 2 while 13 had a grade of 3 and 4. In the DLE group, 19 had a MMI of 1 and 2 and 12 had a MMI grade of 3 and 4.

Logistic regression analysis

Table 14:

	P value	Odds ratio	95.0% C.I.for EXP(B)	
			Lower	Upper
BMI(<25)	.242	.448	.117	1.721
Neck circumference(>34.25)	.077	3.733	.869	16.036
A-O extension(<19.5 ^{O})	.072	3.639	.890	14.878
MCLS(2b&above)	.000	11.687	3.209	42.566
MMI(3&4)	.590	1.452	.373	5.649

Table 15:

	P value	Odds ratio	90.0% C.I.for EXP(B)	
			Lower	Upper
BMI(<25)	.242	.448	.145	1.386
Neck circumference(>34.25)	.077	3.733	1.098	12.686
A-O extension(<19.5 ^{O})	.072	3.639	1.116	11.864
MCLS(2b&above)	.000	11.687	3.950	34.579
MMI(3&4)	.590	1.452	.465	4.541

On logistic regression analysis, it was found that with a 95 % CI only MCLS was found to be a statistically significant predictor with an odds ratio of 12

However with a 90 % CI neck circumference, A-O extension and MCLS was found to be significant with an odds ratio of 4, 4 and 12 respectively

DISCUSSION

In laryngology practice, it is inevitable that clinicians will encounter patients for whom rigid laryngoscopy is either not possible or, at best, suboptimal due to an inability to adequately visualize the laryngeal lesions. Therefore it is important to preoperatively assess the difficulty of a laryngeal exposure. We assessed 117 patients of which 31 (26.5%) patients had a difficult laryngeal exposure. Hsiung et al [(1)] had assessed 56 patients of which 19(33.9%) had DLE while Roh et al [(2)] had 13 (17.8%) out of 73 patients with DLE. Pinar et al [(3)] also had a similar value of 22 (23.7%) cases of DLE in the 93 patients assessed.

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Significant risk factors for DLE by univariate analysis

1. *Neck circumference:*

Pinar et al [(3),] Roh et al [(2)] and Hekiert et al [(4)] found that neck circumference was a statistically significant independent predictor in DLE. Hsiung et al [(4)] l, however did not find neck circumference to be significant. In our study, neck circumference was found to be significant with a *p* value of 0.002

2. *Atlanto-occipital extension:*

Only Roh et al [(2)] assessed A-O extension as a parameter for assessment for DLE. But they did not find it to be a statistically significant predictor .In our study this was found to be a significant independent predictor with a *p* value of 0.001. This suggests that restriction in neck movements does affect glottic visualization.

3. *Modified Mallampatti Index (MMI):*

In our study MMI grade 3 and 4 was found to be a significant predictor for DLE with a *p* value of 0.008. But according to Hsiung at al [1],Roh et al[2] and Pinar et al [3] MMI was not found to be a good predictor for DLE while in the study by Hekiert et al [4], it was found to be a good predictor in non obese patients(BMI <30)

4. *Modified Cormack Lehane scoring system (MCLS):* We found that there was a very significant correlation with MCLS scoring and the grading used by us for DLE with a *p* value of 0.000.This was in accordance to the studies done by Roh et al[2], Pinar et al [3] and Hekiert et a [4] who also found a significant correlation between MCLS and DLE.

5. *Body mass index (BMI):* .BMI on univariate analysis had a *p* value of 0.068. Though this was not statistically significant it was taken for further analysis as it was assumed that BMI could be a good predictor.

The cutoff values according to Roh et al [2] for predicting DLE was a body mass index of > 25.0 kg/m2[2].But Hekiert [4] found a good correlation with a BMI of more than 30 kg/m2[4].Pinar et al [3]and Hsiung et al[1] did not find a correlation with BMI for DLE.

Risk factors not found significant for DLE by univariate analysis

1. Gender: Hsiung et al [1] found a significant correlation with gender stating that women had a higher chance of DLE (*p* value of 0.045 with OR of 69.159).The other 3 studies did not find any correlation. In our study also gender was not a statistically significant predictor (*p* value of 0.16).

2.Thyomental distance (TMD): In the study by Pinar et al [3] the thyromental distance in full extension was found to be a statistically significant predictor with a value less than 7.15 cm[3] and the *p* value was 0.002. Roh et al [2] also found thyromental distance in full extension to be a good predictor but the value was < 5.5 cm [2].In neutral position thyromental distance was not found to be a good predictor in either of the studies. Our study also found that thyromental distance in neutral position had a *p* value of 0.217 which was not statistically significant.

3. Horizontal thyromental distance: In our study *p* value of horizontal thyromental distance was 0.250 which was not statistically significant. The other 3 studies also did not show any statistical significance with this parameter.

4. Sternomental distance: According to Pinar et al [3] sternum-mental distance with a value less than 13.9 cm ($p = 0.046$, OR:23.04) was independently associated with difficult laryngeal exposure[3]. Other 3 studies did not find it to be a good predictor. In our study also it was not found to be a good predictor (*p* value 0.925)

5. Ratio of patient's height to TMD (RHTMD): Though this may be a good predictor for difficult intubation we have not found it to be a statistical significant predictor in our study (*p* value of 0.185.). The other 4 studies had not used this parameter for analysis.

6. Thyroid-mandible angle (TMA):

This parameter was assessed only by Roh et al [2] and he had found it to be a statistically significant predictor for DLE with a *p* value of <0.0001. On logistic regression the odds ratio was 1.51. But in our study the *p* value was 0.331 which was not statistically significant.

<u>Significant risk factors for DLE by multivariate analysis</u>

On logistic regression analysis, it was found that with a 95 % CI only MCLS was found to be a statistically significant predictor with an odds ratio of 12.

However with a 90 % CI neck circumference, A-O extension and MCLS was found to be significant with an odds ratio of 4, 4 and 12 respectively. This means that in a patient with a difficult scopy he is 4 times likely to have a neck circumference more than 34.25 cm, 4 times more likely to have A-O extension less than 19.5 degrees and 12 times more likely to have a MCLS score of 3 or 4.

This is the first time that a study of physical parameters predicting DLE has been done in India. The difference in physical attributes of Indians as compared to people in Turkey, Korea, Taiwan, and USA, where the other 4 studies were done, may be the reason why the results are not similar.

<u>Grading for DLE:</u>

We have now proposed a new classification of difficult laryngeal exposure based on the 5 grade MCLS scoring used by anaesthetists.

Grade 1: Full view of vocal cords

Grade 2: Partial view of vocal cords - Anterior Commissure seen only with external compression

Grade 3: Anterior commissure not seen even with external compression

Grade 4: Only posterior 1/3rd vocal cords seen with external compression

Grade 3 and 4 are being taken up as DLE.

The new classification appears to be a simple and practical grading system for evaluating the extent of laryngeal exposure during microlaryngosurgery. In this study, the laryngeal exposure score significantly correlated with the Cormack-Lehane score used by anesthesiologists. This finding implies that patients who are difficult to intubate are likely to represent difficult cases for rigid laryngoscopy. It is also important to note that the well-known parameters of difficult endotracheal intubation may be applied in studies of DLE risks during microlaryngeal surgery. However, the Cormack-Lehane score seems to be broadly defined as only whether the laryngeal view is adequate for endotracheal intubation. In the field of otolaryngology, even a subtle difference of vocal fold exposure can affect the outcomes of microlaryngeal surgery. Therefore, the Cormack-Lehane score may not be appropriately applied in the DLE studies, and a sub classification of laryngeal exposure according to the extent of vocal fold visualization needs to be established. This will be helpful in communication between otolaryngologists, as well as in further study of DLE. The grading system of glottic visualization enabled us to identify the potential parameters for predicting DLE in a clinical setting.

Limitations of the study:

1. Interobserver variation could not be checked

2. Though sample size was 110, there were 117 cases but 3 values were missing in physical measurements due to inadequate recording. MCLS was missing in 8 cases as it was not mentioned in the anaesthesia records.

Summary:

1. Laryngeal exposure for microlaryngoscopy correlates well with that for intubation:
   MCLS grade more than 2a has an odds ratio (OR) of 12 in predicting DLE
2. Limited neck extension of less than 19.5 degrees has an odds ratio of 4 for predicting DLE
3. Neck circumference of more than 34.25 has an odds ratio of 4 in predicting DLE.
4. Of the 117 cases there were only seven cases with complications. Of these seven, six had a difficult laryngeal exposure

CONCLUSION:

The predictors of **D**ifficult **L**aryngeal **E**xposure were found to be Modified Cormack Lahane Score more than 2a, neck extension of less than 19.5 degrees and neck circumference of more than 34.25 cms. The proposed grading system is a simple tool which can be employed in any set up by otolaryngologists in preparation for microlaryngoscopy.

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Appendix A

Informed consents

Informed Consent form to participate in a clinical trial
Study Title: “Clinical Predictors of Difficult Laryngeal Exposure (DLE)”
Study Number:
Subject’s Initials: _________ Subject’s Name: ________
Date of Birth / Age:_______
Please initial box
(Subject)
(i) I confirm that I have read and understood the information sheet dated _________ for the above study and have had the opportunity to ask questions. [ ]
(ii) I understand that my participation in the study is voluntary and that I am
free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]
(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor’s behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]
(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]
(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____________
Date: _____/_____/______
Signatory’s Name: _________________________________

Signature of the Investigator: ________________________
Date: _____/_____/______
Study Investigator’s Name: _________________________

Signature of the Witness: ___________________________
Date:_____/_____/_______
Name of the Witness: ______________________________

Information sheet

Study Title: "Clinical predictors of difficult laryngeal Exposure (DLE)"

Purpose of research: You have been found to have a disease involving your voice box and will be undergoing a procedure to remove/biopsy the disease. By this study we are trying to find out if any complications are to be expected during the procedure so that we can be prepared for it during the procedure. You will be assessed by a routine examination of the head and neck.

Expected duration of the Subject's participation: You will be examined only once –the day before your surgery.

Description of the procedures:

The procedure to remove/biopsy the lesion in your voice box involves putting a scope through your mouth to see the vocal cords clearly .We will be examining your head and neck to see if that is going to be easily possible in you or whether another scope have to be used for you. All investigations, surgery and medical treatment will be the same for you whether you agree to do this or not. There is no difference to the management of your disease.

Risks or discomforts to the Subject: As the study doesn't include any trial treatment, so there is no extra risk for patient due to participation in study and there will not be any additional cost of treatment for patient due to participation in study.

Benefits to the Subject: Benefits might be reasonably be expected to the subject as an outcome of participation in this study as the surgeon will be better informed regarding difficult laryngeal exposure and you will be contributing in helping future patients.

Benefits to others: Benefits might be expected to others or what new knowledge might occur as a result of this study includes that outcome may help in preventing complications and to be ready if complications do arise.

Confidentiality: Patient's identity will not be revealed in any information released to third parties or published.

Participation: Patient's participation in the study is voluntary and patient is free to withdraw at any time, without giving any reason. Refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled.

Contact person: Dr Roshna Rose Paul , Dept of E.N.T. , CMCH , Vellore

ஆராய்ச்சியில் பங்குபெறுவோருக்கான ஒப்புதல் அறிக்கை

ஆராய்ச்சியின் தலைப்பு:

குரல்வளையை நோக்குவதில் ஏற்படும் கஷ்டங்களை மருத்துவ முறையில் கண்டறிதல்.

ஆராய்ச்சியின் நோக்கம்:

உங்கள்குல்வளையில் நோய் இருப்பதாக கண்டுபிடிக்கப்பட்டு அதற்காக குரல்வளையில் இருந்து சிறிய அளவு திசு எடுப்பதற்காக ஒரு சிகிச்சை அளிக்கப்படும். இந்த படிப்பின் மூலமாக இந்த சிகிச்சையில் ஏதாவது பின் விளைவுகள் உள்ளதா என்பதை அறிய முற்படுகிறோம். இதன் மூலமாக அறுவை சிகிச்சையில் பின்விளைவுகளை சந்திக்க எங்களால் தயாராக முடியும். உங்கள் கழுத்து மற்றும் தலையில் சிறிய பரிசோதனை செய்யப்படும். உடலை துளைக்கும் எந்தவித பரிசோதனையும் செய்யப்படமாட்டாது.

ஆராய்ச்சியில் பங்குபெறுவோருக்கான கால தவணை:

ஒரே ஒரு நாள் உங்கள் அறுவைச்சிகிச்சையின் முந்தைய நாள் மட்டும் பரிசோதிக்கப்படுவீர்கள்.

பரிசோதனையின் விளக்கம்:

உங்கள் குரல்வளையிலுள்ள கட்டியை நீக்குவதற்காக உங்கள் வாயின் வழியாக சிறிய குழல் (Scope) உட்செலுத்தப்பட்டுஉங்கள் மூச்சுக்குழல் ஸ்கோப்பின் வழியாக நன்றாக கவனிக்கப்படும். உங்கள் தலை மற்றும் கழுத்து பரிசோதனை செய்யப்பட்டு இலகுவாக இதனை செய்யமுடியுமா அல்லது வேறு ஸ்கோப் உபயோகிக்க வேண்டுமா என்று முடிவு செய்ய வேண்டும். நீங்கள் இந்த ஆராய்ச்சியில் கலந்து கொண்டாலும், கொள்ளாவிட்டாலும் உங்களுடைய பரிசோதனைகள், அறுவைச்சிகிச்சை மற்றும் சிகிச்சை முறையில் எந்தவித மாற்றமும் இருக்காது.

ஆராய்ச்சியில் கலந்து கொள்பவருக்கு ஏற்படும் அசௌகரியங்கள்:

இந்த ஆராய்ச்சியில் எந்த புதுவிமான மருந்தோ அல்லது வேறு ஏதும் உபயோகிக்கப்படாததால் எந்தவித ஆபத்தோ அல்லது வேறு அதிகச் செலவுகளோ இல்லை.

ஆராய்ச்சியில பங்குபெறுவருக்கான நன்மைகள்:

இந்த ஆராய்ச்சியில் பங்கு பெறுவதன் மூலமாக அறுவை சிகிச்சையின் மூலம் ஏற்படும் பின்விளைவுகள் மற்றும் மயக்கமாக இருக்கும் நேரம் குறைக்கப்படுகிறது.

பிறருக்கும் ஏற்டும் நன்மைகள்:

இந்த ஆராய்ச்சியின் மூலமாக ஏற்படும் அறிவானது பிறருக்கு அறுவைச்சிகிச்சையின் போது ஏற்படும் பின்விளைவுகளை அறிந்து சிகிச்சை அளிக்கவும் அல்லது பின் விளைவுகள் ஏற்படாத வண்ணம் பாதுகாக்கவும் பயன்படுகிறது.

வாக்குறுதி:

நீங்கள் இந்த ஆராய்ச்சியில் கலந்து கொள்வதாகவோ அல்லது ஆராய்ச்சி முடிவுகளோ வேற யாருக்கும் அறிவிக்கப்படமாட்டாது.

பங்குபெறுதல்:

இந்த ஆராய்ச்சியில் பங்குபெறுதல் உங்கள் சுயவிருப்பத்தை பொறுத்தது. இதில் இருந்து விலகவோ அல்லது மறுப்போ அளிக்க பூரண உரிமை உண்டு எந்த வித காரணமும் அளிக்க தேவையில்லை. இதை மறுப்பதால் உங்கள் சிகிச்சை முறையில் எந்தவித மாற்றமும் இருக்காது.

டாக்டர் ரோஸ்னா.

Informed consent

নাম –

জন্ম দিন –

১। আমি জানি যে আমি প্রশ্ন করতে পারি আর আমি সেটা করে নিয়েছি।

২। আমি জানি যে আমি আমার ইচ্ছাতে সহযোগিতা দেব আর আমি আমার ইচ্ছামত ছাড়তে পারব।

৩। আমি জানি যে আমার নাম কিছুতেই আসবে না।

৪। আমি সহমত করতে রাজি আছি।

সই –

তারিখ –

ডাঃ সই –

তারিখ –

Information sheet

সমস্যা – 'পরিষ্কার মাইক্রো দিয়ে আপনার ~~গলার~~ গলা (Larynx) দেখার পরিকল্পনা দেখা হবে।'

কি কারণ – আপনার গলায় একটা অসুখ দেখা গেছে। এই অসুখের জন্য আপনার গলার পরিষ্কার জন্য অন্য সার্জারির নিয়ে অসুখের পরিস্থিতি দেখা হবে। আমরা এই সার্জিক্যাল মাইক্রো দিয়ে দেখতে চাই যে আপনার কোন অসুবিধা দেখা দেবে কিনা। আমাদের আগে থেকে জানা থাকলে আমরা প্রস্তুত থাকব।

কত দিন করা হবে – আপনাকে সার্জারির আগের দিন শুধু একবার পরীক্ষা করা হবে।

কি করা হবে – আপনার সার্জারির পরীক্ষা করার জন্য আপনার গলা দিয়ে একটা যন্ত্র (scope) ঢোকানো হবে। আমরা আপনার মাথা ও গলা পরীক্ষা করে দেখব আর তার মাইক্রো দিয়ে অন্য কোন যন্ত্রের দরকার পড়বে কিনা সেটাও দেখা হবে। আপনার চিকিৎসাতে কোন জটিলতা বা কম হবে না যদিও আপনি সহযোগ দিতে রাজি না হন।

আপনার ক্ষতিকর — আপনার ইহা পাওয়ার কিছু নেই। আপনার আগ্রহ থাকলে এই প্রক্রিয়াতে নিজেকে রাখতে পারেন। আপনার চিকিৎসাতে কোন বেশি খরচ কিছু হবে না।

আপনার সুবিধা — আপনার শারীরিক সমস্যা ক্ষতিকর কম হবে এবং এ ক্ষেত্রে সবসময় আপনি খুব সুস্থ থাকবেন।

অন্যদের সুবিধা — এই পরীক্ষার মাধ্যমে দিয়ে আমরা পরবর্তী কালে ক্ষতিকর কম করতে পারব।

গোপনতা — আপনার সহযোগিতার কথা আর কাউকে বলা হবে না।

সহযোগিতা — আপনার সহযোগিতা সম্পূর্ণ আপনার উপরে। আর আপনি যখন আপনার ইচ্ছা মত ছাড়তে পারেন বিনা কোন কারণ বলে। আপনার চিকিৎসার উপর কোন গাফিলতা করা হবে না।

contact person —
Dr. Roshna Paul,
Dept. of ENT,
CMC & H, Vellore.

Appendix B

PERFORMA

- **age,**
- **sex,**
- **height**
- **weight**

modified Mallampatti index (MMI),	**I/II**	**III/IV**
body mass index (BMI),	**<25**	**>25**
thyroid-mental distance (TMD),	**<5.5**	**>5.5**
horizontal thyroid distance (HTD),	**<4**	**>4**
MCLS	**<2b**	**>2b**
Neck circumference	**<39.5**	**>39.5**
Sternomental distance (SMD	**<12**	**>12**
Thyroid-mandible angle (TMA)	**<120**	**>120**
	<130	**>130**
A-O extension	**<35^0**	**>35^0**

Dx

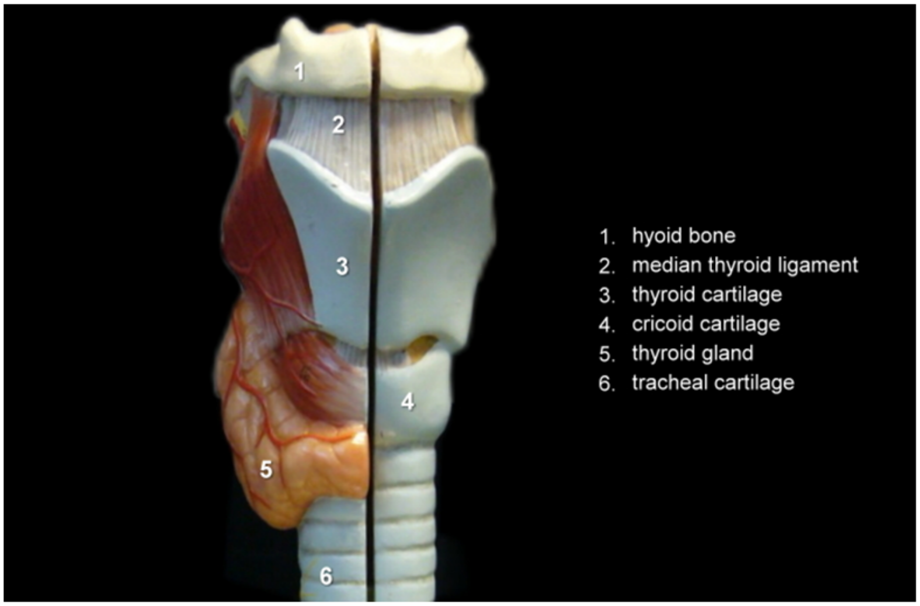
Surgeon : Registrar/consultant

Grade : I /II /III /IV

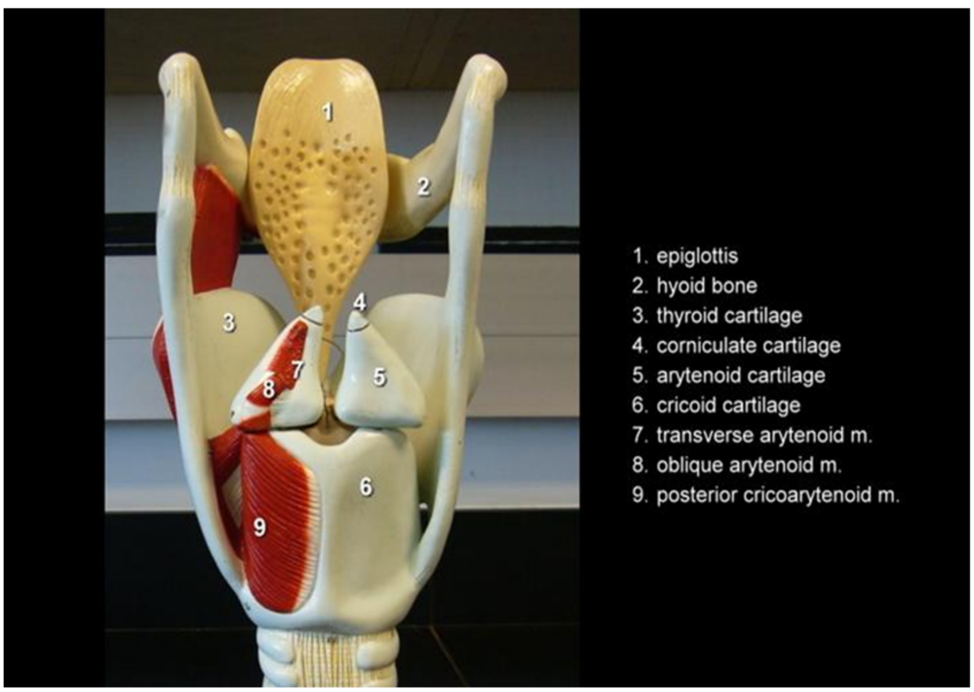
Complications:

Grade 1: Full view of vocal cords: Grade 2: Ant. Commissure not seen but seen on giving external pressure: Grade 3:Anterior commissure not seen even after giving external compression: Grade 4 :Less than half of vocal cords seen

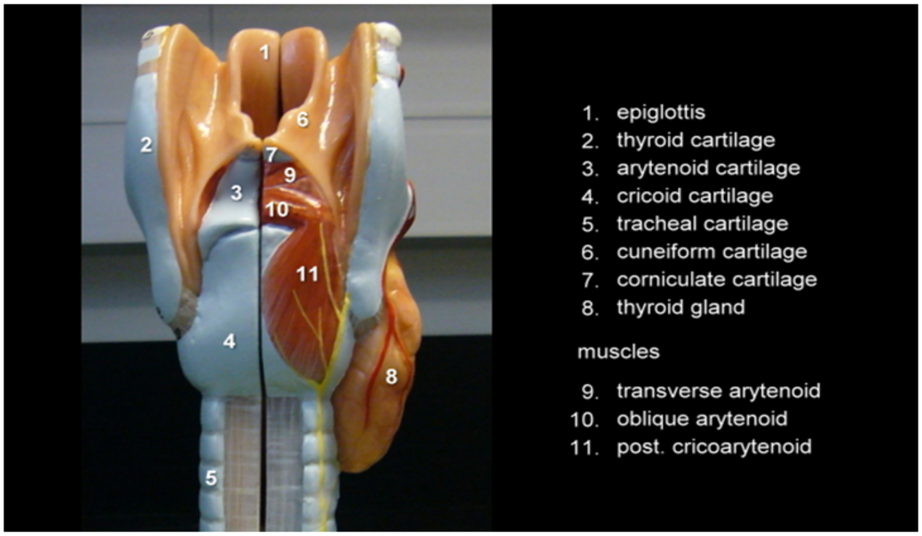
Picture 1



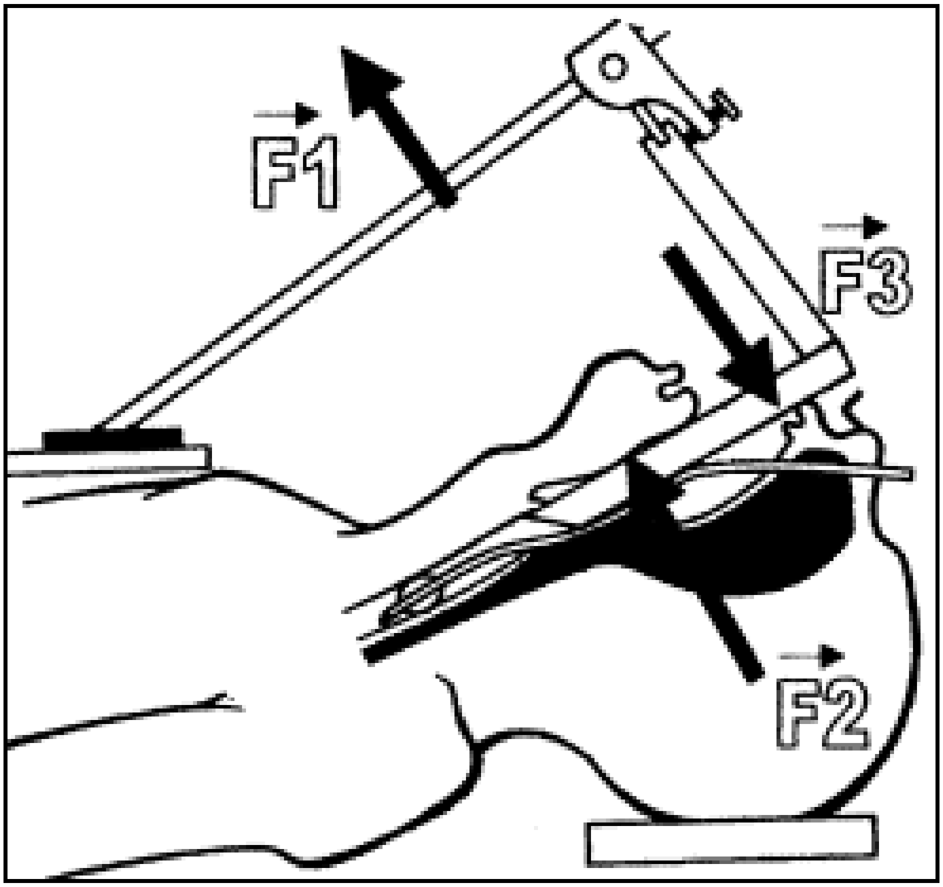
Picture 2



Picture 2


1
2
3
4
5
6
7
8
9
10
11
1. epiglottis
2. thyroid cartilage
3. arytenoid cartilage
4. cricoid cartilage
5. tracheal cartilage
6. cuneiform cartilage
7. corniculate cartilage
8. thyroid gland
muscles
9. transverse arytenoid
10. oblique arytenoid
11. post. cricoarytenoid

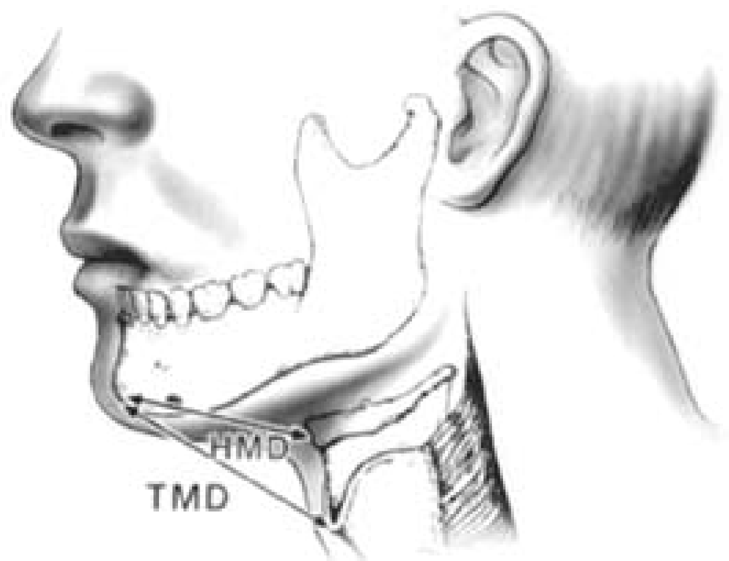
Picture 4[19]



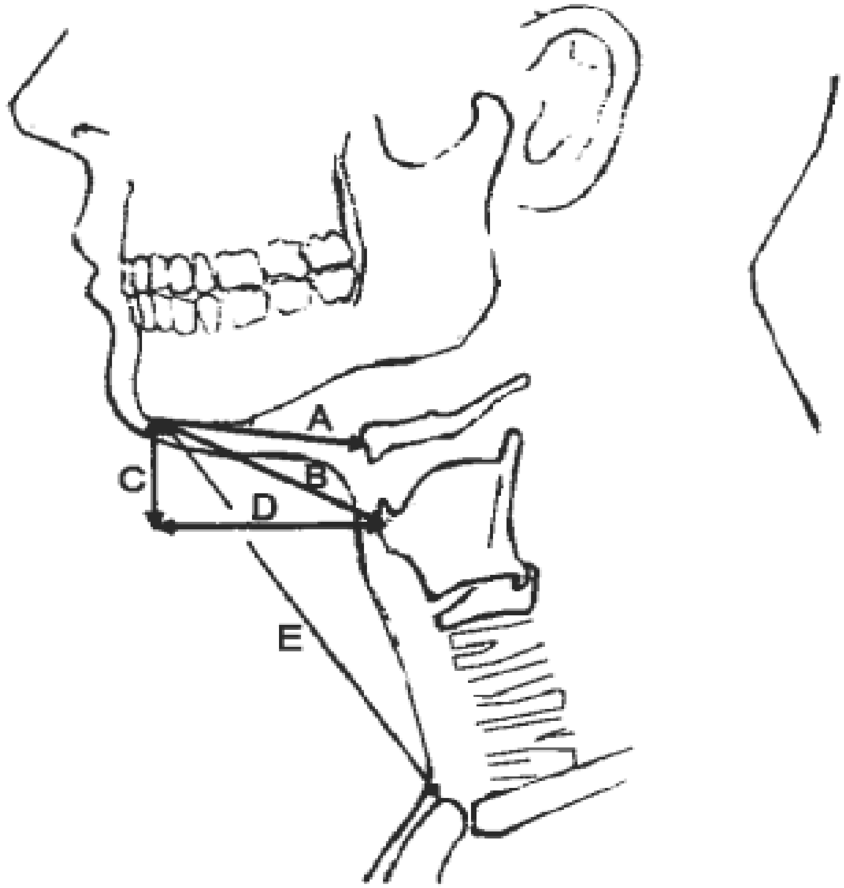
Vectorial forces applied to the patient by the standard laryngoscope holder.
F1: Force applied to the long lever arm
F2: Force within the larynx and tongue
F3: Force directed onto the upper alveolus or teeth

Thyromental distance

Picture 5[1]



Picture 6 [3]



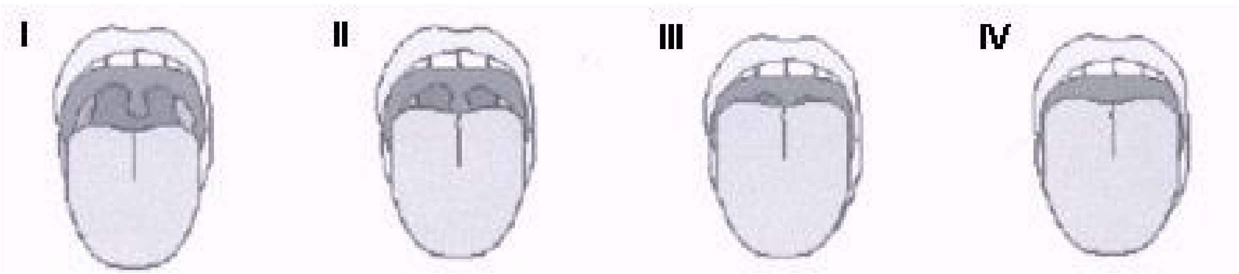
Measurements of physical parameters. **a** Hyoid-mental distance,

b Thyroid-mental distance, **c** Vertical Thyroid-mental distance,

d Horizontal Thyroid-mental distance, **e** Sternum-mental distance

Modified Mallampatti Index

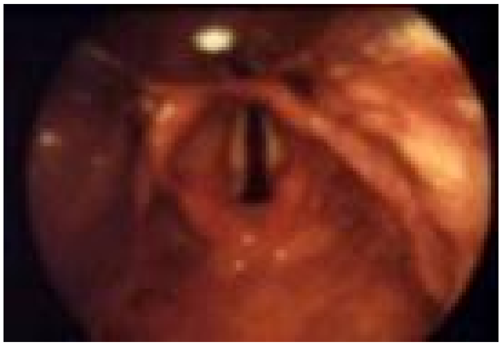
Picture 7



Modified Cormack Lehane scoring

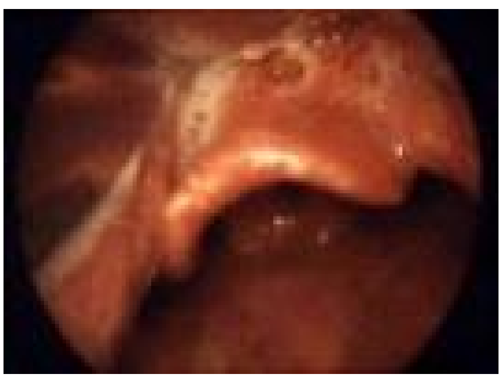
Grade 1

Picture 8



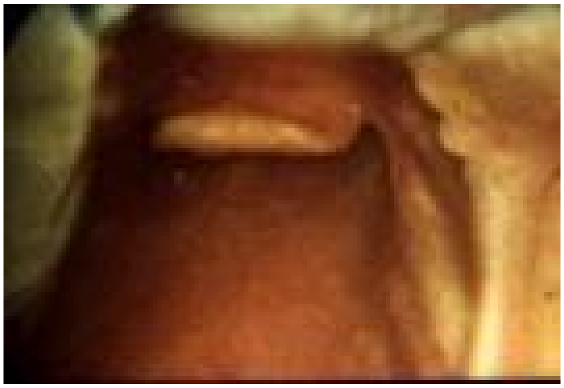
Grade 2

Picture 9



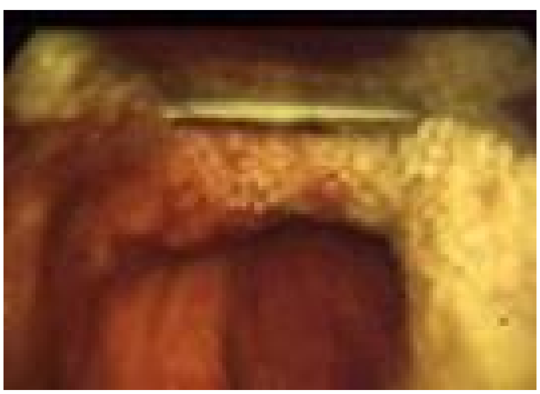
Grade 3

Picture 3



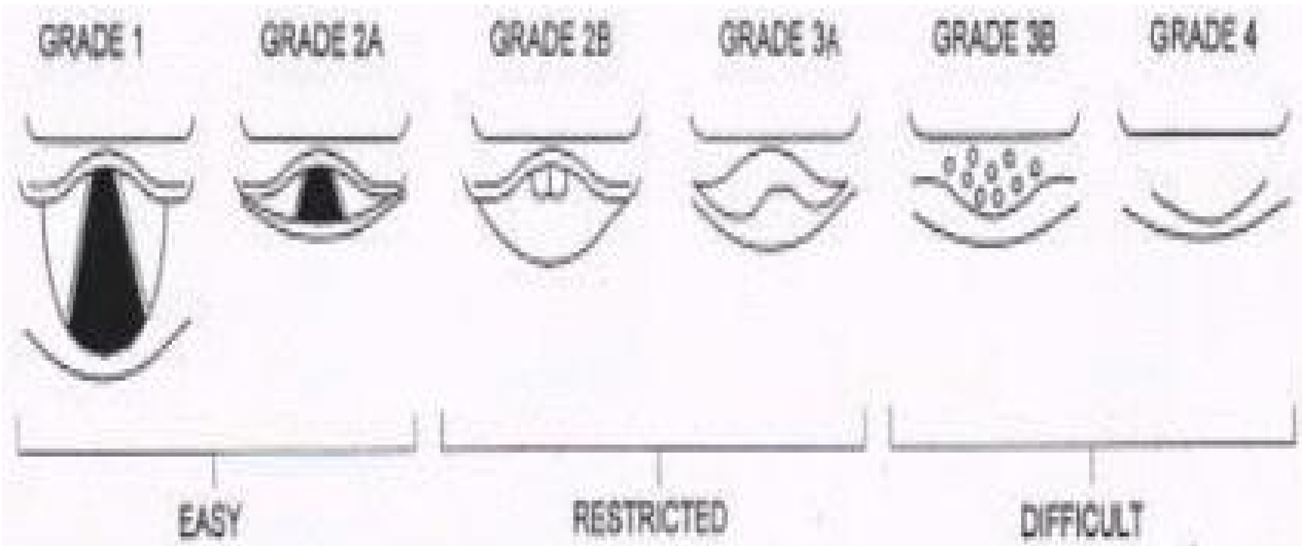
Grade 4

Picture 11



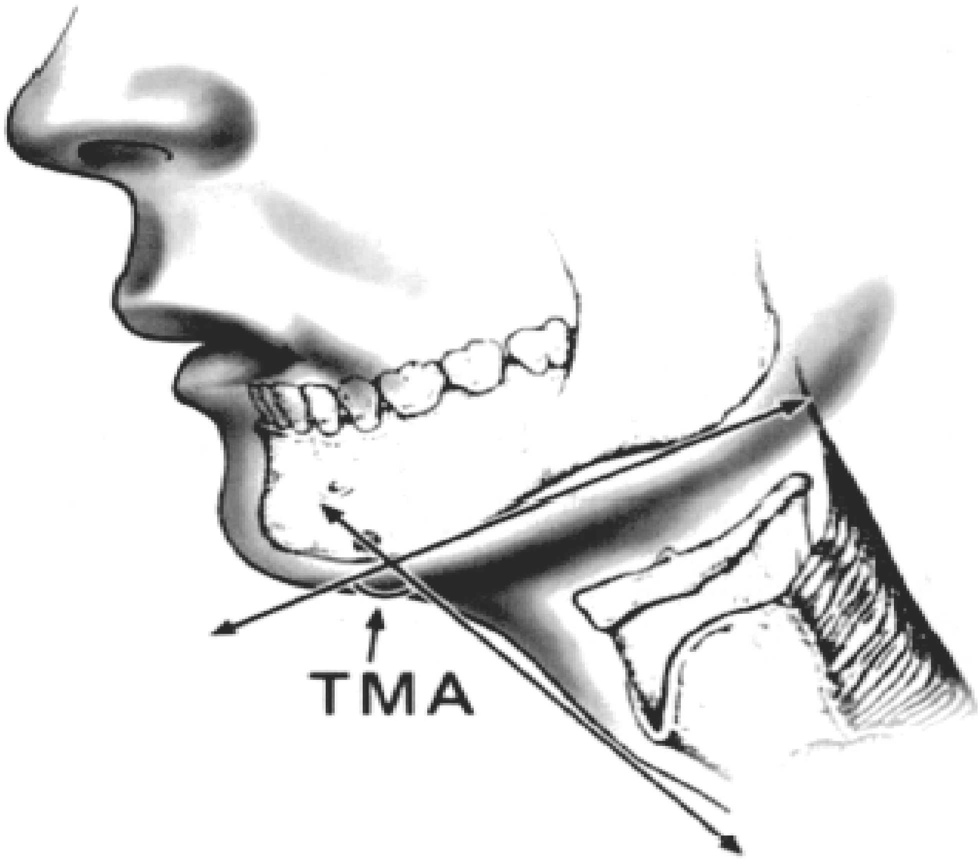
5 Grade MCLS

Picture 12



Thyromandibular angle

Picture 13 [(1)]



Picture 14

Picture 15